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R&D Inc. and Norton (Waterford) Ltd.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL	:	Consolidated Civ. Action No.
	:	20-10172 (JXN) (MAH)
PRODUCTS R&D, INC., and	:	
NORTON (WATERFORD) LTD.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	
	:	
CIPLA LTD.,	:	
	:	
Defendant.	:	
	:	

PLAINTIFFS TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC. AND NORTON (WATERFORD) LTD.'S PROPOSED POSTTRIAL FINDINGS OF FACT ADDRESSING VALIDITY

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I. Introduction

1. This is an action for patent infringement under 35 U.S.C. § 281 and the patent laws of the United States.

2. In this litigation, Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd. (collectively, "Teva") allege that Cipla Ltd.'s ("Cipla's") submission of Abbreviated New Drug Application ("ANDA") No. 211434 infringes claims 1, 2, 4, 6 and 7 of U.S. Patent No. 9,463,289 (the "'289 Patent"); claims 1, 2, 4, 6, 7 and 12 of the U.S. Patent No. 9,808,587 (the "'587 Patent"); and claim 28 of U.S. Patent No. 10,561,808 (the "'808 Patent") (collectively, the "Asserted Claims").

3. Teva further alleges that the commercial manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product would infringe the Asserted Claims.

4. Teva's allegations and requests for relief are set forth in the Joint Pretrial Order. *See* D.E. 210.

II. The Challenged Claims and Priority Date

5. Cipla asserts that claims 1, 2, 4, 6, and 7 of the '289 Patent, claims 1, 2, 4, 6, 7 and 12 of the '587 Patent, and claim 28 of the '808 Patent are invalid for obviousness. For the reasons described *infra*, Cipla has failed to meet its burden to prove invalidity by clear-and-convincing evidence.

6. Cipla asserts that the earliest possible priority date of the Asserted Claims is May 18, 2010. D.E. 257, ¶¶ 8, 12, 16. Teva asserts that the claims are entitled to an earlier priority date of November 2009. Tr. 671:5-12 (Lewis). The Court need not resolve this dispute, because Cipla does not rely on any prior art published in between these two dates, and thus the dispute does not impact the result of the obviousness analysis in this case. *See* Tr. 671:21-672:2 (Lewis) (noting that "analysis with respect to the obviousness opinions" would "not change" if the priority date was in 2010 instead of in 2009).

III. The Disputed Issues

7. For purposes of Teva's responsive submissions, the disputed issues are as follows:

a. Whether Cipla has proven by clear-and-convincing evidence that the Asserted Claims of the '289 and '587 Patents would have been obvious over International Patent Publication No. WO 2007/124406 (the "'406 Publication") in combination with International Patent Publication No. 2003/101514 (the "'514 Publication").

b. Whether Cipla has proven by clear-and-convincing evidence that claim 28 of the '808 Patent would have been obvious over the '406 Publication.

c. Whether Cipla has proven by clear-and-convincing evidence that claim 28 of the '808 Patent would have been obvious over

International Patent Publication No. WO 2008/119552 (the "'552 Publication").

d. Whether Teva is entitled to a declaration and judgment that the '289, '587, and '808 Patents are not invalid.

e. As Teva's Proposed Findings of Fact and co-filed brief explain in greater detail, each of these issues involves a number of additional, subsidiary issues, including whether Cipla has proven by clear-and-convincing evidence that the person of ordinary skill in the art ("POSA") would have a reason or motivation to select, combine, or references that it asserts render obvious the Asserted Claims; and whether the POSA would have had a reasonable expectation of success in doing so.

8. Teva's opening submissions (D.E. 262, 263, 254) address the other disputed issues, including whether Cipla infringes the Asserted Claims, whether objective indicia of nonobviousness support the validity of the Asserted Claims, and whether the Court should admit Teva's submission of Aurobindo evidence (D.E. 234).

IV. Plaintiffs' Development of Inhalers and Dose Counters

9. In 1995, Teva developed a dose counter for its Spiromax product. Tr. 67:25-69:6, 100:11-12 (Walsh); PTX-216 (Presentation). Spiromax is a dry-powder

inhaler that contains medication in powdered, not "liquid form." Tr. 68:12-16 (Walsh).

10. Around 2006, Teva developed a dose counter for its Easi Breathe product. Tr. 67:25-69:6 (Walsh); PTX-216 (Presentation). Both Spiromax and Easi Breathe products are breath-actuated inhalers, which "automatically dispense[] the dose as [patients] inhale through the inhaler." Tr. 68:7-69:6 (Walsh).

11. Subsequently, in 2008, Teva began developing a dose counter to be used with the ProAir® metered dose inhaler ("MDI"), a *hand*-actuated inhaler. Tr. 67:13-24, 101:2-4 (Walsh); PTX-216 (Presentation).

12. Unlike breath-actuated inhalers, MDIs (i.e., hand-actuated inhalers) are not activated by a person's breath. Tr. 68:7-69:6 (Walsh); 625:6-23 (Karg). Instead, hand-actuated inhalers are activated when a patient physically presses down on the canister of the device. Tr. 68:7-70:9 (Walsh).

13. Further, breath-actuated inhalers use a different counting mechanism than hand-actuated inhalers. Breath-actuated inhalers have "an automated mechanism" that registers a count "reliably each and every time" a patient takes a breath. Tr. 69:7-71:1, 114:25-115:7 (Walsh). By contrast, a hand-actuated inhaler is "not a reliable mechanism" because patients press down on the canister in "different way[s]"—for example, some might press it quickly and hard," while others "might press it lightly"—that might not register a count. Tr. 69:7-71:1 (Walsh).

14. In view of 2003 FDA Guidance (PTX-402), which recommended that all new MDIs in development include a dose counting mechanism, i.e., a dose counter or dose indicator, Tr. 153:4-11 (Lewis), Teva began considering integrating a dose counter in its ProAir® MDI product. Tr. 66:22-67:12 (Walsh). Dose counters are essential for patients because they provide "much needed" information about the number of doses remaining in patients' canisters. Tr. 66:22-67:12 (Walsh). However, the 2003 FDA Guidance did not provide a technical solution to the problems associated with the integrating a dose counter into an MDI. PTX-402 (FDA Guidance).

15. Teva considered acquiring dose counting mechanisms from third parties, rather than developing a dose counter in-house. Tr. 72:11-75:10 (Walsh). Those third -party alternatives did not include ribs. Tr. 72:11-75:9 (Walsh); DTX-21 (Presentation). Teva considered dose counting mechanisms from Valois (now Aptar Pharma), Landmark®, and Trudell Medical. Tr. 72:21-24 (Walsh); DTX-106. None of these devices, however, were suitable. Tr. 72:25-73:1 (Walsh).

16. Most of the third-party alternatives that Teva considered were dose *indicators*, the display of which is not as granular as a dose counter's display. Tr. 73:3-12 (Walsh). While dose indicators are easier to develop than dose counters because the display mechanism on a dose indicator can move in "far smaller increments," Teva wanted to provide its patients with more granular displays like those dose counters. Tr. 73:13-19 (Walsh).

17. Teva also received a presentation from 3M regarding its dose counter. Tr. 116:13-117:21 (Walsh). However, 3M never shared a model or designs of the dose counter, and the images that 3M did share did not depict any support ribs. Tr. 116:15-24 (Walsh). Moreover, at the time 3M shared the presentation with Teva, the 3M dose counter was not a finished product. Tr. 116:25-117:21 (Walsh).

18. In addition, Teva considered implementing the dose counter it developed for its Easi Breathe product in its ProAir® MDI. Tr. 103:18-24 (Walsh). But Teva's inventors realized that it was not "easy" to take Easi Breathe's dose counter "and just stick it in ProAir®." Tr. 114:25-115:7 (Walsh); 625:24-626:12 (Karg). Teva's inventors performed mathematical analysis that confirmed as much. Tr. 627:12-628:24 (Karg). Given the difference between breath-actuated inhalers and hand-actuated inhalers, Teva's inventors would have to design around the variability in stroke length to ensure that a hand-actuated inhaler registered a count each time the patient actuated the device. Tr. 69:10-71:1 (Walsh).

19. This notwithstanding, Teva decided to develop its own dose counter and modify the dose counter from its Easi Breathe device and integrate it into the ProAir® MDI device. Tr. 71:6-72:5, 75:11-24 (Walsh); PTX-216 (Presentation). At the early stages of the development process, Teva's inventors considered multiple, potential modifications that were necessary to integrate this dose counter. Tr. 71:6-72:5 (Walsh); PTX-216 (Presentation). None of those potential changes included

adding support ribs to the inhaler body or a regulator to the dose counter. Tr. 72:6-10 (Walsh).

20. During the first phase of development, Teva conducted a feasibility study to determine whether it was technically feasible to develop a dose counter for a hand-held actuator. Tr. 75:11-76:7 (Walsh). The results of that study showed that while such a project was feasible, there would be numerous challenges. Tr. 76:3-7 (Walsh). Moreover, nothing in the feasibility study revealed that it would be necessary to add support rails to the inhaler body or a regulator to the dose counter. Tr. 76:7-11 (Walsh).

21. After conducting the feasibility assessment, Teva entered into the development detail design phase of the project. Tr. 76:14-19 (Walsh). During this phase, Teva engaged Radius Product Development ("Radius"), a U.S. based company, to assist with product development. Tr. 76:22-24 (Walsh); PTX-208 (DFM/DFA Report). Among other things, Radius completed a design for manufacture and design for assembly report, which discussed the key elements of the ProAir® MDI project. Tr. 77:7-16 (Walsh); PTX-208 (DFM/DFA Report); *see also* Tr. 621:22-623:4 (Karg).

22. Further, in collaborating with Radius, Teva decided to locate the dose counter "at the back" and "down towards the bottom" of the inhaler. Tr. 77:17-23 (Walsh). During this phase, Teva's inventors discovered that the ProAir® MDI device was experiencing canister-rocking issues. Tr. 77:17-79:15 (Walsh). Specifically,

the rocking of the canister would cause the counter "to count too soon or too late," which could lead to undercounting and overcounting. Tr. 77:17-79:15 (Walsh).

23. Overcounting occurs when a dose counter counts down without an actuation of the medicament canister. Tr. 77:17-79:15 (Walsh). This is problematic because a patient can dispose of his or her inhaler prematurely, leading to waste. Tr. 77:17-79:15 (Walsh). On the other hand, undercounting occurs when a dose counter does not register a count even though the patient has actuated the device. Tr. 77:17-79:15 (Walsh). When a dose counter undercounts, a patient might believe that he or she has more medication remaining in their canister than they actually do. Tr. 77:17-79:15 (Walsh). This is especially problematic because it heightens the possibility of an emergency, and could even lead to death. Tr. 77:17-79:15 (Walsh).

24. Through a sensitivity analysis, Teva discovered that, from a mechanical standpoint, a patient has to press straight down on the canister—i.e., keeping the canister in a vertical position as long as possible—to engage the actuation member and register the correct count. Tr. 79:16-80:8 (Walsh); Tr. 633:17-24 (Karg). If the medicament canister is rocking or tilting during the actuation, the patient might not correctly press down on the canister, and might pull the canister or push the canister over against the ribs in the inhaler. Tr. 79:16-80:8 (Walsh). Doing so impacts where and how the medicament canister engages the actuation member, which could lead to overcounting or undercounting. Tr. 79:16-80:8 (Walsh). Before the research and

development of this project, Teva did not realize that canister rocking could be a potential problem. Tr. 80:13-16 (Walsh); 633:25-634:20 (Karg).

25. To address this problem, Teva's team of inventors decided to modify the ribs of the inhaler body by adding to the inhaler body a rib that was aligned in a "common plane with the central outlet port and the actuation member." Tr. 77:17-78:18 (Walsh). They did so only after conducting group "brainstorming" sessions. Tr. 64:1-66:10, 83:3-84:7 (Walsh). Thus, it unsurprising that Mr. Walsh did not recall exactly which of Teva's inventors came up with the idea.

26. Moreover, Mr. Karg testified that the inventors came up with the common plane configuration only after performing a detailed "sensitivity analysis," which involved generating "thousands" of mathematical models. Tr. 629:25-635:8; PTX-223 (CETOL Model); PTX-231 (Engineering Drawing). Mr. Karg testified that devices such as Flovent® did not require ribs because the dose counter was attached to the canister and therefore "always able to exactly control the relationship between the canister and the counter." Tr. 638:13-639:14.

27. Modifying the inhaler body carried risks and challenges. For example, adding or modifying rails could affect the resistance of airflow through the device. Tr. 81:25-82:17 (Walsh). Increasing airflow resistance could make it more difficult for a patient to get the medicament into his or her lungs. Tr. 627:2-11 (Karg). From Teva's perspective, it was important not to design the ProAir® MDI product in a way that changed airflow resistance. Tr. 81:25-82:17 (Walsh).

28. Moreover, adding components, such as a rib to the inhaler body, amplify the complexity surrounding the design of the device. Tr. 82:18-83:2 (Walsh). Teva's inventors explained that inhalers are complex systems, and any changes to those systems requires extensive testing. Tr. 82:18-83:2 (Walsh); *see also* 631:24-632:4 (Karg).

29. Separately, during the development of the ProAir® MDI product, Teva's inventors discovered that there were other issues in addition to canister rocking. Tr. 85:22-86:2 (Walsh). Specifically, the counter display was not maintaining accuracy because it had the "ability to move back and forth [on] its own accord." Tr. 85:22-86:2 (Walsh).

30. This is problematic because it diminishes the accuracy of the information that the counter display conveys to the patient, who must know how much medicament remains in his or canister. Tr. 86:3-8 (Walsh). Teva's inventors convened a brainstorming session and considered several ideas to resolve the counter-display issue in Teva's dose counters. Tr. 87:7-90:1 (Walsh); PTX-247 (Brainstorm).

31. Ultimately, Teva developed the regulator in order to regulate the movement of the counter display to incremental movements and ensure accuracy. Tr. 86:9-18 (Walsh); 635:25-636:24 (Karg); PTX-231 (Engineering Drawing). Specifically, Teva developed features on the chassis of the dose counter to reduce the movement of the counter display, preventing it from "float[ing] freely." Tr. 635:24-636:24 (Karg). Like the addition of the rib in the common plane configuration, the addition of the regulator was not a risk-free proposition. The inventors did not want to create

too much strain inside of the dose, which could lead to other components breaking. Tr. 636:25-637:13 (Karg).

32. As part of the development of the dose counter, Teva conducted multiple tests on the dose counter during the engineering phase of the project. Tr. 90:7:91:25 (Walsh). Teva conducted an iterative process of testing—namely, designing the components and then manufacturing and testing them. Tr. 92:1-95:1 (Walsh). During each iteration of testing, Teva had to work through multiple issues and propose solutions to those issues. Tr. 92:1-95:1 (Walsh).

33. In the end, Mr. Walsh testified that Teva developed dose counters that "are as accurate, if not more accurate," than other dose counters on the market. 90:7-91:25 (Walsh). Mr. Walsh also stated that this was one of the most complex programs that he had ever worked on. Tr. 96:14-97:16 (Walsh).

V. Person of Ordinary Skill in the Art

34. The POSA for the Asserted Claims as of the priority dates would have had the skills, education, and expertise of a team of individuals working together to research, develop, and manufacture an inhalation aerosol product with a dose counter. Such a team would have included one or more individuals with master's degrees in mechanical engineering, design engineering, or related fields, with at least two years of post-graduate experience in developing inhalation aerosol products, or bachelor's degrees in similar fields of study, with a commensurate increase in their years of postgraduate experience. Such a team also would have been familiar with a variety of

issues relevant to researching, developing, and manufacturing inhalation aerosol products with dose counters. The team also would have had access to an individual with a medical degree and experience in treating patients with inhalation aerosol devices. Thus, the POSA would have had the knowledge and skills of a physician.

35. Cipla's expert, Mr. Anderson, testified that the appropriate definition of the POSA was someone with at least a bachelor's degree in pharma science or a related discipline with at least two to three years of product development experience with the design and manufacture of metered dose inhalers. Tr. 547:15-25.

36. Teva's expert Dr. Lewis testified that it was appropriate to include a physician in the definition of a person of ordinary skill in the art because the inventions claimed in the Asserted Patents are "going to be used by patients." Tr. 729:21-730:11. Cipla's definition did not include the skills of a physician. *Id.*

37. Indeed, Teva's expert Dr. Panettieri, who has more than thirty years of experience in treating pulmonary disorders and has prescribed inhaler, testified that he has served as a consultant to pharmaceutical companies. Tr. 800:12-801:19, 803:4-10, 804:7-805:2. In his role as a consultant, Dr. Panettieri has advised several companies on inhalers, including "what goes into an inhaler, the medications in them, as well as the use of the inhalers by patients." Tr. 803:4-10.

VI. The Art Reflected Difficulty in Creating Accurate Dose Counters

38. Although Cipla's Proposed Findings of Fact (D.E. 250, § VI) focuses on a select number of prior art references, the prior art disclosed a multitude of

approaches to—and difficulties with—designing MDIs and dose counters. FDA's 2003 Guidance (PTX-402), discussed in the section above, warned that without a dose counter or dose indicator, patients would be left to "guess how many doses are left," leading them to attempt to "use the product when it may be beyond its recommended number of doses and risk not receiving the correct dose" or "throw away" a product that "may still contain acceptable metered doses." Tr. 152:22-153:22 (Lewis). In the latter case, the patient would not "get the medicine they need." Tr. 153:23-154:11 (Lewis). As a result, FDA recommended that MDI manufacturers add dose counters or dose indicators to their products. Tr. 154:12-156:9 (Lewis).

39. Nevertheless, despite FDA's recommendation, developing effective dose counters proved difficult. For example, MDIs must accommodate use by tens of millions of patients with different physical characteristics and unpredictable behaviors. Tr. 149:6-22 (Lewis) ("When we put products to market, we are looking for 10 to 20 million people using the inhalers, typically, on a successful product."). Indeed, Teva's development of the inhalers and dose counters at issue in this case demonstrates. As Mr. Karg, one of the named inventor's testified, it was "very hard to develop a counter that would work with the users variable engagement with the product." Tr. 626:7-12 (Karg).

40. MDIs are also difficult to design because they form part of an interdependent system; changing one component has unpredictable consequences on other components. *See* Tr. 145:5-14 ("Most of the time this is not going to work."),

703:6-13 ("[I]n the first instance, you can't take one device to another and combine it."), 706:15-21 ("[Y]ou can't mix and match things."), Tr. 751:18-22 (Lewis); Tr. 659:1-4 (Karg) ("It was an entire system. The hardest part was understanding the interplay of all of the different components and then building a solution set that would work . . . for everything we had to modify.").

41. MDIs are also fundamentally medicinal products. The purpose of an MDI is to deliver medicine to a patient's lungs. Any changes to the MDI (including the addition of an integrated dose counter) affect drug delivery by changing the "flow path" through the device. Tr. 685:20-24 (Lewis) ("You start putting anything inside, you are going to change the flow path. Once you put a patient's mouth in front of this, there is going to be backflow. Anything you put upstream, it is going to have a big change in how, essentially, the medicine reaches the lungs."). Any interference with drug delivery is a "deal breaker," Tr. 684:21-685:6 (Lewis), and even "small changes" to product performance can prove "extremely important" or "potentially fatal"—and could entail 10 to 20 years of development work. Tr. 746:9-23 (Lewis).

42. As explained below in greater detail, these difficulties would have been especially significant in the case of the particular prior art references that Cipla asserted at trial. *See infra* §§ VII, VII.C, IX.

VII. The Asserted Claims of the '289 Patent Would Not Have Been Obvious

43. Cipla failed to prove by clear-and-convincing evidence that claims 1, 2, 4, 6, and 7 of the '289 Patent are invalid for obviousness. *See infra* §§ VII.B-VII.C.

44. Claim 1 of the '289 Patent recites:

> 1. An inhaler for metered dose inhalation, the inhaler comprising:
>
> a main body having a canister housing,
>
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
>
> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
>
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and
>
> wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port,
>
> the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

45. Asserted claims 2, 4, 6, and 7 each depend from claim 1 and therefore incorporate every limitation of claim 1.

A. Cipla Agrees Teva's Inventions Are New

46. Teva's inventors contributed a key discovery to the field of metered dose inhalers. Tr. 170:15-171:8 (Lewis). Teva's inventors realized that arranging key components of the MDI could reduce the effect of canister rocking on dose counter accuracy. *Id.* Teva's solution to the rocking problem involved aligning three parts of the inhaler—an inner wall canister support formation of the inhaler body, an actuation member of the dose counter, and the center of the central outlet port of the inhaler body in a straight line. Tr. 172:10-25, 173:15-176:3 (Lewis); PTX-411 (Cipla ANDA Product Sample). Teva's inventors were the first to make this discovery, which is embodied in the '289 Patent in the form of the Common Plane Limitation, which is a feature of every claim in the '289 Patent. JTX-003 ('289 Patent); Tr. 173:1-4, 173:15-176:8, 208:5-24 (Lewis).

47. Cipla does not dispute that Teva's invention is new, because it failed to identify any single publication that disclosed every limitation of claim 1 of the '289 Patent, nor any publication whatsoever that disclosed the Common Plane Limitation. Tr. 563:21-564:4 (Anderson), Tr. 672:3-19, 673:10-12 (Lewis).

B. The Asserted Claims of the Common Plane Patents Would Not Have been Obvious Over the '406 Publication in Combination with the '514 Publication

48. Cipla offered testimony in support of its invalidity defense through a single expert, Mr. Anderson, who testified only that the asserted claims of the '289

Patent would have been obvious to the POSA in light of the '406 Publication and the '514 Publication in combination. Tr. 563:21-564:4 (Anderson).

49. Mr. Anderson's conclusory testimony failed to establish by clear-and-convincing evidence that claims 1, 2, 4, 6 and 7 of the '289 Patent would have been obvious to the POSA as of the relevant priority date, particularly in view of Dr. Lewis's contrary testimony. *Infra* §§ VII.A-VII.C Dr. Lewis has more than twenty-five years' experience developing metered dose inhalers and has led research and development of metered dose inhalers at multiple multi-national pharmaceutical companies. *See* Tr. 125:1-136:21 (Lewis); PTX-026 (Curriculum Vitae).

1. The POSA Would Not Have Been Motivated to Combine the Ribs of the '514 Publication with the Dose Counter and Inhaler of the '406 Publication

50. Cipla failed to establish by clear-and-convincing evidence that the POSA would have been motivated to combine the ribs of the '514 Publication with the dose counter and inhaler of the '406 Publication. *Infra* §§ VII.B.1.a-VII.B.1.d.

a. The POSA Would Not Have Selected the Inhaler and Dose Counter of the '406 Publication for Combination with the '514 Publication from the Sea of Prior Art

51. The prior art reflected a wide range of available dose counters and dose indicators from which the POSA could have chosen to begin the effort to comply with the FDA's guidance that MDI manufacturers should integrate dose counters or dose indicators into their products. Tr. 675:22-680:4 (Lewis).

52. The prior art also reflected a wide range of support rail configurations for use in MDIs, Tr. 697:14-701:12 (Lewis), including MDIs *without* support rails. Tr. 698:1-4 (Lewis).

53. Cipla's expert, Mr. Anderson, did not offer any opinion regarding why the POSA would have plucked the inhaler and dose counter of the '406 Publication and the ribs of the '514 Publication out of the sea of prior art for combination. Tr. 597:7-14 (Anderson), 597:7-14 (Lewis), 692:4-21 (Lewis).

54. Cipla's expert explained no reason why the POSA would have selected the inhaler and dose counter of the '406 Publication for modification. Tr. 597:7-14 (Anderson), Tr. 692:4-21 (Lewis). Instead, Mr. Anderson explained, the '406 Publication was "the one that we're talking about as far as the dose counters are concerned" –he confirmed there was not any other reaons why he selected it for modification, or why, in his opinion, the POSA would have done so. Tr. 597:7-14 (Anderson) ("Q. Any other reason? A. No").

55. Dr. Lewis explained numerous reasons why the POSA would in fact *have avoided* the inhaler and dose counter of the '406 Publication as a starting point. Tr. 675:12-693:4 (Lewis); PTX-148 (Stuart article). Rather, he explained that the POSA would have faced a number of design choices and would have been led away from the '406 Publication at every turn. *Id.* Dr. Lewis's testimony was corroborated by a 2013 article by Mr. Stuart, an inventor of the '406 Publication. PTX-148 (Stuart article). The Stuart article was published a few years after the date of Teva's invention, but

nevertheless reflects the state of the art and the challenges the POSA would have faced as of the date of Teva's invention. Tr. 678:20-679:12 (Lewis).

56. Cipla offered no evidence that if the POSA did not select the '406 Publication for combination with the '514 Publication, the POSA would not have arrived at the inventions of the asserted claims of the '289 Patent. Tr. 692:16-21 (Lewis); Tr. 563:21-564:4 (Anderson).

57. Because the POSA would have avoided selecting the '406 Publication for modification, Cipla failed to establish by clear-and-convincing evidence that the asserted claims of the '289 Patent would have been obvious. *Infra* § VII.B.1.a.

1) The POSA Would Have Made an Indicator, Not a Counter

58. If the POSA had set out in 2009 or 2019 to comply with FDA guidance that manufacturers should integrate a dose counter or indicator into their MDIs, the first design choice the POSA would have faced would have been whether to make a counter or an indicator. Tr. 675:12-676:5 (Lewis).

59. Mr. Anderson did not address the choice between a counter and an indicator. Tr. 597:7-14 (Anderson); Tr. 679:18-21 (Lewis). Dr. Lewis testified that the POSA would have chosen "most definitely" to make an indicator, not a counter. Tr. 676:5-18, 679:13-17 (Lewis). His testimony was supported by the Stuart article. PTX-148 (Stuart article).

60. The POSA would have chosen to make an indicator rather than a dose counter, because indicators are "a much simpler problem," that would have been "cheaper," and faster to develop. Tr. 676:5-18 (Lewis). Dose indicators also have larger displays and do not need to include as many printed numbers, since they may count down in intervals of ten or twenty, or can even use color schemes rather than numbers. Tr. 677:12-678:18 (Lewis). This can be important for MDIs, which often have up to 200 doses, and it can be difficult to fit that many numbers on the display indicator in a font that patients can see. *Id.*; PTX-148, at TEVADOC-00000532, TEVADOC-00000534 (Stuart article).

61. If the POSA chose to make an indicator rather than a counter, the POSA would not have selected the '406 Publication for modification, nor would the POSA have arrived at the invention of the '289 Patent, because each asserted claim requires a dose counter. Tr. 679:22-680:4 (Lewis); JTX-3 ('289 Patent. Claims 1, 2, 4, 6, 7).

2) If the POSA Chose to Make a Counter, the POSA Would Have Located it Outside the Inhaler Body

62. The next design choice the POSA would have faced when seeking to apply the FDA's guidance would have been where to locate the dose counter. Tr. 680:18-21 (Lewis).

63. Mr. Anderson did not address the choice of location for the dose counter. Tr. 597:7-14 (Anderson), 687:14-20 (Lewis). Dr. Lewis testified that the

POSA would have chosen to locate the counter on the top of the canister or on the side of the inhaler body, and would have *avoided* placing the counter inside the inhaler body, as the '406 Publication does. Tr. 680:22-697:13 (Lewis); DTX-161 ('406 Publication). His testimony was supported by the Stuart article. PTX-148, at TEVADOC-00000532 (Stuart article).

64. The POSA would not have selected a dose counter located inside the inhaler body for modification, but instead would have chosen to work with a top- or side-mounted inhaler body. Tr. 680:22-697:13 (Lewis). Dr. Lewis explained that not only would the POSA have preferred an external location, but the POSA would have actively *avoided* an internal one:

> Q. So what about placing the dose counter inside the inhaler body?
>
> A. *I wouldn't do that.* . . . If you are adding something in line, inside the inhaler, you are changing how the flow is going to move. You will change the medication. There is lot of work involved in then demonstrating clinically that you haven't made that product ineffective.

Tr. 683:20-22 (emphasis added).

> Q. So, then, getting back to the decisions that the skilled person would make, if the POSA in 2009 chose to make a dose counter, where would the POSA have chosen to put it?
>
> A. It's got to go on the top. My personal first choice, it's going to go on the front. That's a nice place to put it. You're probably going to go for the back or the side afterwards. *Anything inside I wouldn't be thinking of. I would be avoiding that.*

Tr. 687:6-13 (emphasis added). One disadvantage to an internal location was size—"there is not a lot of space in an inhaler" and "you will have to make things fit" which would require "chang[ing] the body of the inhaler to maybe make all that work and fit." Tr. 684:7-15 (Lewis); PTX-148 at TEVADOC-00000532 ("Fitting a dose counter or indicator inside the actuator is a very difficult task, as the space envelope between the MDI valve and actuator is typically very small."). Most importantly, the POSA would have understood that a top-mounted counter interferes with the inhaler the least, because while it does add the complication of an additional component, it does not "obstruct[] any of the delivery of the medicine, the way the inhaler moves, any of the components." Tr. 681:2-11, 682:7-16 (Lewis). While top-mounted counters had some disadvantages, the POSA would have understood that the advantages of locating the counter on the top of the inhaler outweighed the strong reasons to avoid disadvantages. Tr. 682:20-23 (Lewis).

65. Thus, the POSA would *not* have selected a dose counter located inside the inhaler body. As the POSA would have understood, an "internal dose counter or indicator sitting in the upstream airflow of the [MDI] has the potential to disrupt the spray plume of the medication. Tr. 685:7-686:3; PTX-148, at TEVADOC-00000532 (Stuart article). The POSA would have appreciated that "[a]ny thing you put upstream, it is going to have a big change in how . . . the medicine reaches the lung," which could make the inhaler clinically ineffective. Tr. 683:20-684:6, 685:13-686:3 (Lewis). The POSA would also have understood that the lack of space inside the

inhaler could require changes to the inhaler body to accommodate a counter, which creates lots of additional problems to solve. Tr. 684:8-15 (Lewis). The POSA would have understood these disadvantages to outweigh advantages such as not changing the appearance of the inhaler to the patient, because the POSA would have viewed delivering medication consistently as the most important consideration—the POSA would have seen it as "deal breaker" if a dose counter interfered with medication delivery. Tr. 684:18-685:6 (Lewis); PTX-148, at TEVADOC-00000533-534 (Stuart article).

66. Mr. Stuart's article explained that "the most critical factor to be considered during the development of a dose counter for an MDI is the effect its presence will have on dose delivery performance," PTX-148, at TEVADOC-00000533, and explained the challenges associated with internal counters, TEVADOC-00000532-535. His article thus corroborated Dr. Stuart's testimony that the POSA would have prioritized drug delivery over other concerns, and that side and top mounted counters were best situated to avoid drug delivery problems. PTX-148, at TEVADOC-00000532-35 (Stuart article). Dr. Stuart's publication highlights that "[a]n internal dose counter or indicator sits in the upstream airflow of the MDI, which ahs the potential to disrupt the spray plume," PTX-148 at TEVADOC-00000532, and also that "airflow is a key consideration, as a change or restriction in airflow could lead to a significant change in the geometry of the spray plume and the efficiency of delivery to the lungs," PTX-148 at TEVADOC-00000534. Mr. Stuart made clear that

"[t]his criterion is less of a consideration for top- or side- mounted dose counters because the counter does not sit directly in the critical airflow path" but that it is a concern for internal dose counters, which "need to be designed so that they do not restrict airflow or considerably affect the flow profile between the valve and mouthpieces in the bottom of the actuator." PTX-148 at TEVADOC-00000534. As Dr. Lewis explained, "Stuart is highlighting if we're going to keep drug delivery consistent, don't put it inside the upflow." Thus, even years after publishing his invention in the '406 Publication, its inventor was thus cautioning against using the approach employed in the '406 Publication, where the dose counter is located internally. Tr. 686:22-687:5 (Lewis). The Stuart article did not reference the '406 Publication or otherwise suggest that the '406 Publication had solved these problems. PTX-148.

67. If the POSA chose to make a top- or side-mounted dose counter, the POSA would not have selected the '406 Publication for modification, nor would the POSA have arrived at the inventions of the asserted claims of the '289 Patent. Tr. 687:21-688:8 (Lewis); DTX-161 ('406 Publication).

3) If the POSA Made A Counter and Placed It Inside the Inhaler, the POSA Would Have Affixed the Counter to the Canister

68. The next design decision the POSA would have faced in 2010 would have been whether or not to affix the counter to the canister. Tr. 259:2-260:6, 688:24-689:5 (Lewis).

69. Mr. Anderson did not address the choice of whether or not the POSA would have affixed the dose counter to the canister. Tr. 597:7-14 (Anderson), 690:17-21 (Lewis). Dr. Lewis explained that the POSA would have chosen to affix the counter to the canister, contrary to the approach of the '406 Publication. Tr. 689:6-691:4 (Lewis); DTX-161 ('406 Publication).

70. As of the date of Teva's invention, there was one MDI with a dose counter on the market, called Seretide. Tr. 689:6-13 (Lewis). Seretide's dose counter was located inside the housing and was affixed to the canister. Tr. 689:14-690:9 (Lewis). If the POSA chose to make a counter and chose to locate it inside the inhaler housing, Seretide's approach would have caused the POSA to affix the counter to the canister. Tr. 690:10-691:4 (Lewis).

71. Affixing the dose counter to the canister comes with substantial advantages—namely, it eliminates the potential for inaccuracy-inducing rocking between the canister and the dose counter, is particularly robust, and assists in handling and assembly of a complete dispenser, including by facilitating the insertion of the canister/counter assembly into the inhaler body. Tr. 259:1-260:6 (Lewis) ("If you affix it to the canister, if you fix the dose counter to the canister, you don't have to solve the rocking problem because it is fixed to the canister; DTX-165 at 7:20-27 ('514 Publication) ("The provision of a dispensing canister/indicator assembly as a self-contained or single unit in which the indicator is located substantially about the dispensing canister (e.g. the container of the canister and/or the canister closure

means and above the outlet means of the canister is particularly advantageous because such an assembly is desirably robust. Furthermore such an assembly allows for desirable ease in handling and assembly of a complete dispenser. In particular the insertion of the outlet means into the support block of an adaptor is desirably facilitated for large scale assembly and more importantly if desired by a patient because the outlet means of the dispensing canister is unobstructed by components of a dose counter.").

72. If the POSA chose to affix the dose counter to the canister, the POSA would not have selected the '406 Publication for modification because the '406 Publication does not affix its counter to the canister. DTX-161; 567:11-13 (Anderson), 708:23-709:4 (Lewis). Cipla offered no reason why the POSA would have arrived at the claimed invention of the '289 Patent if the POSA had not made this selection. Tr. 690:17-21 (Lewis), 544:13-605:12 (Anderson).

73. Furthermore, if the POSA chose to affix the dose counter to the canister, the POSA would have been led directly away from claim 2 of the '289 Patent, which requires that the dose counter be moveable relative to the canister. Tr. 691:5-23 (Lewis); JTX-003 ('289 Patent, Claim 2).

4) Cipla's Post-Trial Rationale for Selecting the '406 Publication Is Unsupported by the Evidence

74. Cipla suggests that the POSA would have gravitated toward the inhaler and dose counter of the '406 Publication because it was a 3M publication, and 3M was

an important inhaler company. No evidence supports the assertion that 3M authorship would have moved the POSA to select the '406 Publication. Cipla's expert, Mr. Anderson testified only that the inventors of the first MDI worked for a company called Riker that was later acquired by 3M. Tr. 549:7-24 (Anderson). He in no way connected that observation to his later analysis of the '406 Publication. *Id.* Dr. Lewis testified that 3M was a "big name" in inhalers, but did not agree or suggest that the POSA would have selected the '406 Publication as a useful starting point for further modification in view of that fact, let alone that 3M's authorship would have overcome all the many other reasons why the POSA would have understood the '406 Publication to be an unsuitable starting point. Tr. 776:1-10 (Lewis). Dr. Lewis also rejected the idea that 3M's efforts to market a dose-by-dose counter would have encouraged use of the '406 Publication, noting that he saw pictures of a 3M dose-by-dose device, but had "worked with companies who show me pictures and hard designs that they don't function. They are just looking for funding." Tr. 772:14-20, *see also id.* at 772:10-12 (Lewis) ("Does it work? I don't know. I've never seen it. And also we pointed out the airflow is really critical. I don't know."). In fact, Dr. Lewis explained that the '406 Publication was cleverly designed in a way that depended on using specific components in combination, such that the POSA would have avoided making any changes to those components. Tr. 751:18-22 (Lewis) ("The specific '406 patent makes it difficult to move to different components by its very design."). Cipla failed to prove the POSA would have plucked the '406 Publication out of the sea of

prior art merely because it was written by 3M; this fact in isolation would not have overcome the unrebutted evidence regarding the many characteristics making the '406 Publication a poor starting point for further modification.

75. Cipla also suggests that Dr. Lewis endorsed the '406 Publication as a starting point for further modification because he referred to the design as "a great design," Tr. 772:1-12, and "fantastic," Tr. 748:4-20 (Lewis). Cipla mischaracterizes Dr. Lewis's testimony. Dr. Lewis explained that the "fantastic" part of the '406 Publication was its clever stabilization of the canister via a fit between the valve and the dose counter. Tr. 748:4-20 (Lewis). Dr. Lewis was equally clear that if the POSA modified the '406 Publication by altering its components, changing the valve used, or adding rails, the POSA would have destroyed the "fantastic" feature of the '406 Publication. *Id.*; *see also id.* at 747:13-748:3, 794:14-24 (Lewis) ("[N]ot a good idea"). Put differently, Dr. Lewis testified that the '406 Publication might be "a good design" in isolation, but was not a "fantastic" starting point for modification. Tr. 794:14-24; *see also* Tr. 697:14-701:12 (Lewis). The POSA who intended to add rails to a device thus would have avoided the '406 Publication as a starting point. *Infra* § VII.B.1.b.

b. The POSA Would Not Have Been Motivated to Add Support Rails to the '406 Publication

76. Even if the POSA (1) chose to make a dose counter rather than a dose indicator, and (2) chose to locate the counter internally rather than outside the inhaler body, and (3) chose *not* to affix the counter to the canister, and (4) viewed the '406

Publication as a suitable starting point, Cipla failed to establish by clear-and-convincing evidence that the POSA would have had a reason to modify the inhaler of the '406 Publication by adding support rails. *Infra* ¶¶ 77-86.

77. Mr. Anderson emphasized the prevalence of ribs in prior art inhalers. Tr. 570:5-573:1 (Anderson). Mr. Anderson suggested that "any MDI" would have ribs in it. Tr. 575:25-576:4 (Anderson). Mr. Anderson's reliance on the '406 Publication makes clear that assertion is not true—the '406 Publication lacks support rails, Tr. 696:20-22 (Lewis), Tr. 569:22-23 (Anderson), and Dr. Lewis testified that certain marketed inhalers also lacked support rails and that he was working on and developing such inhalers. Tr. 698:1-7 (Lewis); DTX-161 ('406 Publication).

78. Mr. Anderson also testified as to reasons why the POSA would have viewed rails as useful in inhaler bodies generally. Tr. 574:6-576:6 (Anderson). None of those reasons addressed whether the POSA would have had a reason to add ribs to the '406 Publication specifically, nor took account of the structure and function of the '406 Publication. *Id.*

79. In particular, the POSA would have understood that the '406 Publication's unique design does not require support ribs in order to reduce canister rocking. Tr. 752:4-21 (Lewis). Instead, the '406 Publication uses a different method of stabilizing the canister, by selecting a valve "shaped like a top hat" and attached to the bottom of the canister. *Id.* When the canister is depressed, the "top-hat-shaped" bottom of the valve/canister assembly drops into a recess in the dose counter and is

thereby stabilized by the complementary fit. *Id.* at 793:19-21 (Lewis). The POSA would have understood that because of this design, the '406 Publication "doesn't need any stabilization" provided by rails. Tr. 738:7-739:3 (Lewis). Instead, the POSA would have appreciated that "Figure 27 [of the '406 Publication] is a very stable counter. There is a valve which is specific to the design, and that dose counter doesn't need any additional stabilization." *Id.* "As it is designed in the '406, it works without stabilization. It's stabilized because of the valve design." Tr. 748:4-20 (Lewis); *see also* 793:16-21 ("because the ferrule of that valve is sitting on the dose counter, it doesn't need any more support."). Dr. Lewis's testimony was unrebutted.

80. Mr. Anderson did not testify that the POSA would have understood the '406 Publication to suffer from any of the problems, including stabilization, that he suggested rails could solve. *See, e.g.*, 570:6-14 (Anderson). Dr. Lewis confirmed that the POSA using the '406 Publication's inhaler and dose counter would not have expected to experience any of the problems Mr. Anderson identified as reasons for adding support rails to inhalers. Tr. 695:2-11 (Lewis) ("The '406 publication at no point says there's a problem with the design."). Again, Dr. Lewis's testimony was unrebutted on this point.

81. Because the POSA would *not* have believed the '406 Publication suffered from any of the problems Mr. Anderson suggested would or could be solved by the addition of ribs, the POSA would not have had any reason to add ribs to the '406 Publication. Tr. 695:2-696:16 ("There is no reason to make any changes to this"), *Id*

at 697:21-25, 698:8-25 (Lewis). To the contrary, Dr. Lewis testified that the POSA would never make an unnecessary change to an MDI design, because to do so would introduce risk, cost time and money." Tr. 695:12-696:1 (Lewis). Inventor testimony from Mr. Karg confirmed this instinct—he explained that as a design engineering principle, engineers seek to make minimal changes where possible. Tr. 626:14-627:11; PTX-227 at TEVAQVAR-00461312. Mr. Karg explained that:

> [A]ny time you make a change, you really don't know what else – what's going to happen in the rest of the mechanism. It was during this project that I learned the phrase knock-on effects. You know, I would have just called it, you know, you change something and now it doesn't work, but there are always knock-on effects. When you change one thing, there's a spillover down into the rest of the mechanism that you just don't know what's going to happen."

Tr. 626:14-24. Because the POSA would have appreciated that no addition of ribs was necessary, the POSA would have "use[d] the can, the valve, and the housing and . . . the specific parts as designed with this inhaler." Tr. 695:12-19

82. Not only would the POSA have had reason to avoid making unnecessary change, the POSA would also have expected adding ribs to the inhaler and counter of the '406 Publication to be detrimental, and ruin the otherwise "good design" of the '406 Publication. Tr. 794:14-24 (Lewis). Specifically, the POSA would have appreciated that the components of the '406 Publication were tailored closely to one another, such it would be "difficult to move to different components." Tr. 751:18-22 (Lewis). For that reason, Dr. Lewis testified that if the POSA chose to work with the

dose counter of the '406 Publication, the POSA would have used the inhaler body of the '406 Publication, and would have avoided making any changes to its design. Tr. 694:20-696:16 (Lewis). Mr. Karg's testimony regarding the design principle that engineers seek to make "minimal changes" because there are always "knock-on effects" that "spillover" supports this conclusion. Tr. 626:14-627:11 (Karg).

83. The POSA would have appreciated that there was already "a lot of material" in the '406 Publication's inhaler]," and the POSA would have wanted to avoid adding yet more internal components. Tr. 794:5-11 (Lewis). In addition, the POSA would not have "want[ed] to obstruct the movement of that canister which is sitting on the dose counter," because "[i]f you put the rib in, it's not going to work." *Id.*; *see also* Tr. 703:22-704:21 (ribs will "get in the way" of the movement of the canister).

84. Most importantly, Dr. Lewis explained that ribs "impede airflow, and they change how the airflow [in an MDI] occurs. You have to be careful how you put them. So if you can leave them out, as in a number of products that I worked with, then you leave them out." Tr. 779:18-23 (Lewis). In sum, the POSA would have understood that "[i]f you add that extra rib all you are doing is adding to the downsides of this design poor airflow, restriction of drug delivery" which is "not a good idea." Tr. 794:14-24 (Lewis). Cipla suggested that Dr. Lewis's statement in a 2007 article that "four equally spaced ribs" in inhaler bodies "provided an annular passageway to draw air using the mouthpiece" conflicted with his trial testimony that

ribs "don't help airflow. They impede airflow and they change how the airflow occurs." PTX-099 (Lewis 2007 article); Tr. 779:18-25 (Lewis). Cipla is incorrect. Dr. Lewis explained that the truth was "almost the opposite of what [Cipla] [was] implying. Tr. 780:9-781:12 (Lewis). The ribs he was describing in his article were "for the purpose of making sure there is a space" between the canister and the inhaler body, because if the inhaler body is "too tight" around the canister, the inhaler will not work. Tr. 779:18-781:12 (Lewis). That understanding is not inconsistent with Dr. Lewis's trial testimony that where ribs are unnecessary, they should be omitted due to their potential to impede and alter airflow in an otherwise functional inhaler. Tr. 779:18-25 (Lewis) ("They don't help airflow. They impede airflow, and they change how the airflow occurs. You have to be careful how you put them. So if you can leave them out, as in a number of products that I worked with, then you leave them out.").

85. Mr. Anderson did not address any of these concerns. Tr. 570:5-573:1, 574:6-576:6 (Anderson). The evidence shows that in the case of the '406 Publication, the POSA would have expected the addition of ribs to create new problems without providing any of the generalized benefits Mr. Anderson identified. *Infra* § VII.B.1.d; *see* Tr. 574:6-576:6 (Anderson) ("It doesn't cost you anything to add a rib, so why wouldn't you put it in to enhance the product."). The POSA therefore would not have been motivated to add ribs to the inhaler of the '406 Publication.

86. If the POSA did not have a reason to add support rails to the inhaler body of the '406 Publication, the POSA would not have arrived at the inventions of the asserted claims. Tr. 696:20-697:9 (Lewis).

c. The POSA Would Not Have Selected the Ribs of the '514 Publication for Addition to the Inhaler and Counter of the '406 Publication

1) The POSA Would Not Have Had a Reason to Select the Ribs of the '514 Publication

87. Mr. Anderson identified many different references containing support rails, Tr. 570:15-573:1, but explained no reason why the POSA would have selected the four, equally-spaced ribs of the '514 Publication, from among the sea of "rails" art, Tr. 699:1-700:22 (Lewis). To the contrary, Mr. Anderson testified on cross examination that in fact the POSA might have selected different rib configurations: "[I]t could be three. I would recommend that as a minimum. You can put in six. Why would you put in too many, but three minimum." Tr. 603:16-604:2 (Anderson). Mr. Anderson's inconsistent testimony does not support a conclusion that the POSA would have selected, specifically, the four equally-spaced ribs of the '514 Publication for addition to the '405 Publication.

88. Furthermore, Mr. Anderson's reliance on the '514 Publication was founded in hindsight. Cipla now argues that the POSA would have chosen to take that rear rib out of the '514 publication, and put it in the exact same location in a *different* inhaler body using a *different* dose counter. Mr. Anderson did not so testify,

and no evidence support Cipla's argument. Nevertheless, Cipla now asserts that such a choice would *just so happen* to cause the rib to line up in a Common Plane with the center of the central outlet port and an actuation member of the dose counter. Cipla's reliance on the rear rib of the '514 Publication in order to achieve the Common Plane Limitation despite offering no evidence to explain *why* the POSA would have had reason to select the '514 Publication (or a device with a rear-facing rib), Tr. 699:1-700:22, 702:12-16 (Lewis), demonstrates that Mr. Anderson's reliance on the '514 Publication was a hindsight-driven effort to piece together the claimed invention from the prior art, not an objective inquiry into the POSA's motivations in 2010.

89. Dr. Lewis testified without contradiction that the POSA would *not* have selected the rails of the '514 Publication for combination with the inhaler body and dose counter of the '406 Publication. Tr. 703:6-709:8 (Lewis).

90. First, Dr. Lewis explained that the ribs of the '514 Publication were structured such that they were likely to interfere with the operation of the '406 Publication's dose counter. The ribs of the '514 Publication were structured to interact and increment the count of the dose counter of the '514 Publication, Tr. 707:2-10, 708:16-22 (Lewis); DTX-165, at 27 ('514 Publication), which would not have worked or fit with the dose counter of the '406 publication, Tr. 703:6-706:21 (Lewis).

2) The POSA Would Not Have Disregarded the '514 Publication's Core Principle of Operation

91. More fundamentally, the POSA would have understood that the core principle of the '514 Publication is the decision to affix the dose counter to the canister. Tr. 707:2-709:8 (Lewis). In the '514 Publication, the counter is affixed to the canister, the two components move downwards together, and the counter strikes one of the ribs, which causes the count to increment. Tr. 708:16-22 (Lewis); DTX-165 ('514 Publication) at 27-28 and Fig. 8a (rib that actuates dose counter colored yellow)

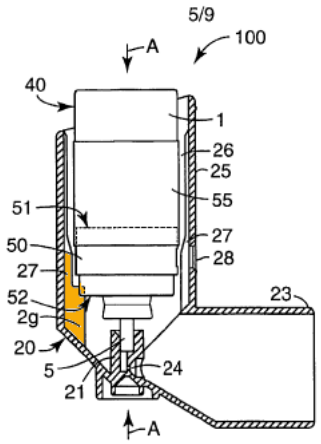


Fig. 8a

Thus, the ribs of the '514 Publication are especially adapted to work with the counter of the '514 Publication. *Id.* The '514 Publication is "all about fixing the dose counter to the canister" and repeats that principle over and over again. *Id.* at 707:21-708:2; *see generally* DTX-165 ('514 Publication) (describing mounting or attaching dose indicator to canister); *e.g.*, at 1 (title and abstract referring to "canister-indicator assemblies" "wherein said indicator … is arranged to be circumferentially … mountable about the dispensing canister"), 6 ("wherein said indicator is arranged to be circumferentially mountable about the dispensing canister"), 8 ("Annular dose indicators according to

the invention . . . can be easily mounted around the dispensing canister . . .”), 9 (“The provision of a dispensing-canister/indicator assembly as a self-contained or single unit in which the indicator is located substantially about the dispensing canister (e.g. the container of the canister and/or the canister closure means) and above the outlet means of the canister is particularly advantageous because such an assembly is desirably robust.”); 10 (“Preferably the indicator is secured to an external surface of the container”), 14 (“Figure 7 shows a cross sectional view of the preferred annular dose indicator illustrated in Figures 5 and 6 mounted and attached to a dispensing canister of the type depicted in Figure la providing a preferred embodiment of a canister indicator assembly”), 33-37 (all claims requiring an indicator mounted to the canister).

92. Dr. Lewis explained that affixing the dose counter to the canister is a “great idea”, Tr. 708:3-13, that comes with substantial advantages—namely, it eliminates the potential for inaccuracy-inducing rocking between the canister and the dose counter, is particularly robust, and assists in handling and assembly of a complete dispenser, including by facilitating the insertion of the canister/counter assembly into the inhaler body. Tr. 259:1-260:6 (Lewis) (“If you affix it to the canister, . . . you don’t have to solve the rocking problem”); DTX-165 at 7:20-27 (’514 Publication) (“The provision of a dispensing canister/indicator assembly as a self-contained or single unit in which the indicator is located substantially about the dispensing canister (e.g. the container of the canister and/or the canister closure means and above the outlet

means of the canister is particularly advantageous because such an assembly is desirably robust. Furthermore such an assembly allows for desirable ease in handling and assembly of a complete dispenser. In particular the insertion of the outlet means into the support block of an adaptor is desirably facilitated for large scale assembly and more importantly if desired by a patient because the outlet means of the dispensing canister is unobstructed by components of a dose counter.").

93. The POSA who selected the '514 Publication as part of an effort to develop a dose counter would not have taken away from the '514 Publication the use of four, symmetrically-spaced ribs to be transferred to another inhaler body. Tr. 708:3-15 (Lewis). Instead, the POSA would have focused on the idea of affixing the dose counter to the canister, which was the approach taken by the only marketed MDI with an internal dose counter as of 2010. *Id.* (POSA would "take away the fact that you are going to fix the dose counter to the canister.").

94. Furthermore, the POSA would not have combined aspects of the '514 Publication—which emphasizes affixing the counter to the canister—with a reference like the '406 Publication, which discloses a dose counter that is moveable relative to the canister. Tr. 708:23-709:8 (Lewis). To do so would have been to change the core principle of operation of the reference, and would require the POSA to "completely disregard[] the teachings of the '514 [Publication]." *Id.* The POSA would not have pursued such a combination. *Id.* Mr. Anderson did not address this issue.

95. For the reasons described above, the POSA would not have been motivated or had reason to combine the ribs of the '514 Publication with the inhaler body and dose counter of the '406 Publication. *Supra* §§ VII.B.1.a-VII.B.1.c.1). Cipla and Mr. Anderson offered no evidence that if the POSA had not selected the rails of the '514 Publication, the POSA would have arrived at the claimed invention. Tr. 563:21-564:4 (Anderson).

d. The POSA Would Not Have Been Motivated to Combine the '406 and '514 Publications in a Manner that Led to the Claimed Invention

96. Even had Cipla shown that the POSA would have been motivated to combine the ribs of the '514 Publication with the inhaler and dose counter of the '406 Publication, Cipla failed to prove that the POSA would have had reason to combine those features in a manner that (1) would have led to the Common Plane Limitation or (2) would have resulted in the ribs being arranged to reduce canister rocking. *Infra* § VII.B.1.d. The POSA would therefore not have arrived at the claimed invention.

1) The POSA Would Not Have Been Motivated to Add a Rail to the '406 Publication in the Common Plane

a) No evidence Suggests that the POSA would Have Selected a Particular Rib Location

97. Cipla did not offer any evidence to explain why, if the POSA chose to combine the ribs of the '514 Publication with the inhaler body and dose counter of

the '406 Publication, the POSA would have arranged the ribs in a manner that satisfied the Common Plane Limitation. Tr. 576:22-578:9 (Anderson).

98. The undisputed testimony reflected that the POSA would have faced a nearly infinite set of choices regarding where to locate the ribs in the inhaler body of the '406 Publication. Dr. Lewis explained:

> Q. . .. I heard Mr. Anderson testify that there are four evenly spaced rails in Figure 8A of the '514 publication -- . . . how many ways are there to put four evenly spaced rails in an inhaler body?
>
> A. Well, you can put them pretty much anywhere. So certainly back in that period, there were rails being included, but there was no format. Each set of rails would be put into a different place by different inhaler manufacturers if they were included.

Tr. 712:15-24 (Lewis).

> Q. And again, if the POSA took the rails of the '514 publication and put them in an inhaler body with the five castellations of the '406 publication, would that necessarily result in the common plane?
>
> A. Absolutely not. No. It could be arranged in any order.

Tr. 713:20-24 (Lewis).

99. Mr. Anderson agreed that the POSA would have had "a lot of choice" about where to locate ribs, and stated that the POSA must "choose carefully":

> T]he places that you put the rails or the ribs, I mean, ultimately you are given quite a lot of choice. And within the actual space that you are talking about, yet you got to choose carefully -- you do have to choose carefully where you put them. And you do have to think about it.

Tr. 602:25-604:2 (Anderson).

100. The prior art provided no guidance as to how the POSA would have selected among these virtually infinite options. Mr. Anderson did not explain on what basis the POSA would have "cho[sen] carefully," nor how the POSA would have selected a particular location from among the large number of options available. *Id.*

101. At his deposition, Mr. Anderson agreed that "[t]here is no disclosure anywhere in the '406 Publication or the '514 Publication that suggests it is important to put support rails in particular places to prevent canister rocking." Tr. 602:9-604:9 (Anderson). This concession accurately reflects the state of the art.

102. At trial, Mr. Anderson forsook his prior sworn testimony but did not explain any reason why the POSA would have aligned the ribs of the '514 Publication in any particular fashion. Tr. 601:23-604:9 (Anderson). Instead, he asked, "Why would you put them in not an important place?" Tr. 601:23-602:2 (Anderson). Mr. Anderson never explained where the POSA would have understood an important place to be. *Id.*; 602:9-604:9 (Anderson).

103. Dr. Lewis confirmed that nothing in the art would have given the POSA a reason to arrange support rails in any particular location relative to a feature of the dose counter, as the Common Plane Limitation requires:

> Q. And is there any teaching anywhere in the art that Mr. Anderson has identified or that you've seen to arrange support rails in a particular location relative to components of the dose counter?

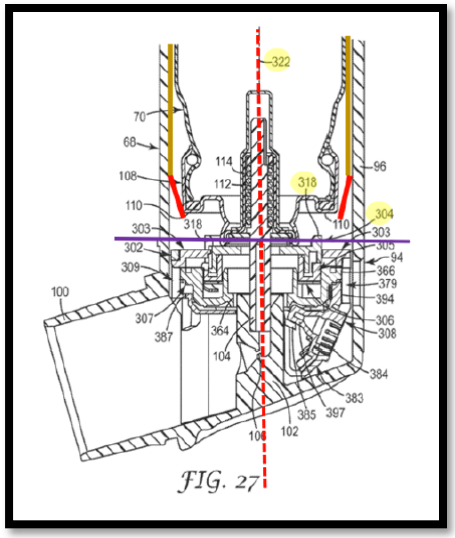
> A. Absolutely not. As I highlighted, I worked with a number of inhalers and developed inhalers and worked with companies with and without rails. No, there was no format.
>
> Q. And does the prior art ever disclose or suggest to the POSA that there is a reason to arrange rails in order to reduce the rocking of the canister and improve counter accuracy?
>
> A. No. Not at all. Never.
>
> Q. Had anyone in the art even appreciated that rocking was a problem that related to dose counter accuracy?
>
> A. At that point it was -- no. It was unknown.
>
> Q. So in the absence of understanding this problem, is there any reason the POSA would have aligned support rails in a common plane, the actuation member of any dose counter?
>
> A. No. There would be no reason at all.

Tr. 712:25-713:19 (Lewis).

b) Mr. Anderson's Testimony Was Irrelevant and Conclusory

104. At trial, Mr. Anderson did not offer any reason whatsoever to explain his opinion that the combination of the ribs of the '514 Publication with the inhaler and dose counter of the '406 Publication would have produced a device that met the common plane limitation. Tr. 576:22-578:9 (Anderson). His entire explanation consisted of two questions and answers, Tr. 576:5-577:8, 577:13-578:9 (Anderson), both related to the below annotated drawing, from DDX3.32, to which Cipla added

the purple line, red, and gold lines, and the yellow highlighting, Tr. 601:4-22 (Anderson); DTX-161 ('405 Publication) (at Fig. 27, showing no annotations). Only the black and white features of the image actually come from the prior art. DTX-161 at Fig. 27.



The red ribs Cipla drew, which are located only at the bottom of the inhaler body and shown as angled flaps, do not resemble the ribs of the '514 Publication (DTX-165 at Fig. 2a, 8a).

105. First, Mr. Anderson testified as follows:

> Q. In view of [the claim construction], can you tell me whether or not the last limitation of the Claim 1 the '289 patent is disclosed in the '406 with the '514?
>
> A. Yes. So with this one, you've got the two components. we have highlighted the axis of the actual cross-section of the '406 product. You can see that it has a longitudinal axis. So we highlighted that, 322. But we've also got the actuation member or the indexer from the '406 publication as well. And again, Claim 1 of '289, it is obvious over the

> '406 publication with the '514. It would have been obvious with the common planes.

Tr. 576:5-577:8 (Anderson). Mr. Anderson's testimony fails to identify the features that must be in the common plane, let alone that the features are aligned in a common plane or where that plane is located in the image above. *Id.* Because this testimony fails even to suggest that Cipla's combination of the '406 and '514 Publications would have resulted in an inhaler that meets the Common Plane Limitation, it necessarily fails to explain why the POSA would have had a reason to align a rib in the Common Plane. *Id.*

106. Next, Mr. Anderson testified as follows:

> Q. Now, I want to ask you why is your opinion that a POSA would have had expectation of success when combining the '406 or the '514 regarding your obviousness opinion on Claim 1 of the '289 patent.
>
> A. So with this one, the last part of that claim, we've got the -- we're in the canister housing, so we've got the longitudinal axis, which passes through the center of the central outlet port. We've got the inner wall support formation. We've got the actuation member. And we've got the line in an axis in a plane coincident with a longitudinal axis. And as we have been discussing, the '514 discloses the inner wall canister support formation. That is the red. We've got the ribs that would be -- again, they would be put in place. If we're looking at a -- the common plane, which is the purple line, that purple line goes through the central outlet port. It goes through the inner wall canister support formation. I'm sorry, the other ribs -- I got that wrong. Apologies. And obviously the actuation member. So in summary, the Claim 1 of the '289 patent would have been obvious over the '406 publication when brought together with the '514 publication.

Tr. 577:13-578:9 (Anderson). This testimony likewise fails to provide clear-and-convincing evidence that if the POSA combined the ribs of the '514 Publication with the inhaler of the '406 Publication, the POSA would have had reason to do so in a way that produced in an inhaler that met the Common Plane Limitation. *Id.* At best, Mr. Anderson explained his opinion that Cipla's annotated drawing shows a purple line connecting the longitudinal axis X of the '406 Publication, an actuation member of the '406 Publication, and a red rib that does not exist in the '406 Publication but that Cipla drew into Figure 27 of the '406 Publication. *Id.* This opinion does not explain why the POSA in 2010 would have had a reason to place the rib of the '514 Publication into the '406 inhaler body at the place Cipla chose to draw it. *Id.* The fact that Cipla can draw a rib into a figure does not answer the salient legal question of whether and why the POSA would have chosen to place a rib at that location in 2010. Cipla thus fails to meet its burden to show, by clear-and-convincing evidence, that the combination of the '406 and '514 Publications would have resulted in the inventions of any of the Asserted Claims.

c) Dr. Lewis Rejected Cipla's Theory

107. Dr. Lewis did not agree that if the POSA combined the '406 and '514 Publications, the result would have been an inhaler that met the Common Plane Limitation, and did not sacrifice his credibility by failing to do so. Dr. Lewis testified both that the POSA would not have made such a combination, and that if the POSA

did so, there is no reason the POSA would have selected, out of the myriad possibilities, an arrangement of ribs that happened to satisfy the Common Plane Limitation. *Supra* § VII.B.1.a.

108. Cipla's reliance on the location of a rib at the rear of the '514 Publication also fails to meet its burden. Mr. Anderson never once identified that fact, referenced its relevance to his theory of obviousness, nor explained its significance. *See* 544:13-605:12 (Anderson). First, Mr. Anderson did not offer any theory of obviousness in which the POSA would have taken the dose counter of the '406 Publication and moved it into the inhaler body of the '514 Publication. Second, Mr. Anderson explained no reason why, under the theory of obviousness he did offer, that the POSA would have excised a rib from the rear of the '514 Publication, and then chosen to place that rib into precisely the same location in a wholly different inhaler body with a dose counter that functioned very differently from that of the '514 Publication—especially in light of the evidence that the ribs of the '514 Publication and inhaler body of the '406 Publication would need to be modified in unspecified ways to accommodate their combination. *Supra* § VII.B.1.c; Tr. 703:6-709:8, 746:4-7 (Lewis).

109. The POSA would not have combined the '406 and '514 Publications in a manner meeting the Common Plane Limitation. *Supra* ¶¶ 97-108-.

2) If Added to the '406 Publication, There is No Evidence the Rails Would Have Been Arranged to Reduce Rocking

110. Cipla failed to address or adduce any evidence that if the rails of the '514 Publication were added to the inhaler body and dose counter of the '406 Publication, the resulting arrangement of rails would have been "arranged to reduce canister rocking" as the construction of "inner wall canister support formation" requires. D.E. 102, at 5.

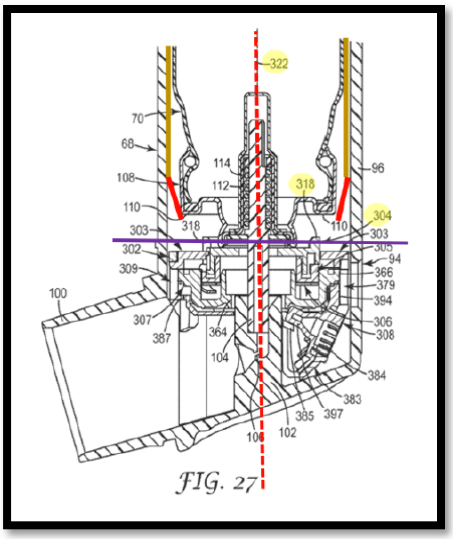
111. Mr. Anderson discussed this issue a single time, did not offer any relevant testimony. Instead, he testified that the ribs of the prior art were not inner wall canister support formations:

> Q. And I know you use the use of ribs here. When you're talking about the claim language, inner wall canister support formation and you walk through that analysis, were you saying the ribs were the same as the inner wall canister support formation?
>
> A. No. They can have two different purposes really. These ones in the prior art, they are used to hold the devices in place. Yeah.

Tr. 573:2-9 (Anderson). He then transitioned to discussing the '514 Publication as though it disclosed inner wall canister support formations. Tr. 573:13-574:5 (Anderson).

112. The statement in the '514 Publication that that ribs "may be positioned within the chamber of the cylindrical portion to aid in locating and supporting the container in the correct position," DTX-165 at 14:18-19 ('514 Publication), is sufficient to meet Cipla's burden. That statement refers to the ribs when have the size and shape shown in the '514 Publication, and they are located in the inhaler body of

the '514 Publication. *Id.* That statement does not reflect whether or why the ribs—if moved into a different inhaler body with a different dose counter—would still be "arranged to reduce canister rocking," especially in light of testimony suggesting that unspecified modifications to the size and shape of the ribs and/or inhaler body would need to be made to accommodate such a combination. *See* Tr. 703:6-709:8 (Lewis) ("it's not going to fit"), 746:4-7 (Anderson). For the same reason, the fact that the rails depicted in the figures of the '514 Publication extend toward the top of the inhaler body does not suggest they would do the same if placed into the '406 Publication—to the contrary, Cipla's graphic representation regarding the results of such a combination, shown in annotated Figure 27 (reproduced below) and DDX3.32, depict the resulting ribs as red flaps located at the bottom of the inhaler body and that do not extend to the top of the inhaler body:



113. Cipla failed to adduce evidence sufficient to show that the ribs of the '514 Publication, if imported into the inhaler body of the '514 Publication in the manner Cipla relies upon, would be "arranged to reduce canister rocking" and thus inner wall canister support formations within the meaning of the Asserted Claims.

114. This conclusion is not inconsistent with Teva's infringement theory. Dr. Lewis analyzed the particular rib located in Cipla's device, and his testimony that its extension into the inhaler body necessarily restricted the canister's freedom of movement was rendered in the context of the shape of that rail and the device in which it was located, as well as the observations he was able to make by physically observing and manipulating Cipla's device. D.E. 263, ¶¶ 44-72. None of those things are possible to analyze in the context of Cipla's imaginary device, as depicted in annotated Figure 27 above.

2. The POSA Would Not Have Reasonably Expected Success in Combining the Rails of the '514 Publication with the Inhaler and Dose Counter of the '406 Publication

115. Cipla also failed to prove by clear-and-convincing evidence that the POSA would have reasonably expected success in adding the rails of the '514 Publication to the inhaler and dose counter of the '406 Publication.

a. Mr. Anderson Failed to Address Expectation of Success

116. Mr. Anderson did not explain why the POSA would have expected to successfully integrate ribs from the '514 Publication into the '406 Publication, and still

produce a functional MDI with an accurate dose counter. Tr. 544:13-605:12 (Anderson).

117. Mr. Anderson repeatedly stated that the POSA would have had a reasonable expectation of success in conclusory fashion but he failed to explain the basis for his opinion. Tr. 564:9-19, 576:4-6, 576:8-12 (Anderson). This testimony—which at most speaks to motivation—does not provide a reasoned analysis as to the separate prong of the obviousness analysis requiring Cipla to prove a reasonable expectation of success.

118. Mr. Anderson was asked precisely one time to explain his expectation of success analysis: "why is your opinion that a POSA would have had expectation of success when combining the '406 or the '514 regarding your obviousness opinion on Claim 1 of the '289 Patent?" Tr. 577:13-16 (Anderson). Mr. Anderson responded:

> A. So with this one, the last part of that claim, we've got the -- we're in the canister housing, so we've got the longitudinal axis, which passes through the center of the central outlet port. We've got the inner wall support formation. We've got the actuation member. And we've got the line in an axis in a plane coincident with a longitudinal axis. And as we have been discussing, the '514 discloses the inner wall canister support formation. That is the red. We've got the ribs that would be -- again, they would be put in place. If we're looking at a -- the common plane, which is the purple line, that purple line goes through the central outlet port. It goes through the inner wall canister support formation. I'm sorry, the other ribs -- I got that wrong. Apologies. And obviously the actuation member. So in summary, the Claim 1 of the '289 patent would have been obvious over the '406 publication when brought together with the '514 publication.

Tr. 577:13-578:9 (Anderson). That analysis does not address the reasonable expectation of success inquiry and Cipla does not rely on it for that purpose. *Id.* Mr. Anderson failed to explain why—if the POSA had chosen to add the ribs of the '514 Publication to the inhaler and dose counter of the '406 Publication—the POSA would have expected the device of the '406 Publication to accommodate those ribs, whether and how that device would need to be adjusted in order to do so, whether such modifications were feasible, and whether the resulting device would have dispensed medicine and counted accurately. *Id.*

119. The single statement in the '406 Publication that its dose counter is designed to "fit compactly within commercially available actuator housing profiles so that it is not necessary to change the external configuration of those actuator housings to accommodate the inventive dose counter therein" is insufficient to meet Cipla's clear-and-convincing burden. DTX-161, at [00105] ('406 Publication). Mr. Anderson did not explain the import of this sentence, likely because it was not relevant to his theory of obviousness, which relied on moving the ribs from the '514 Publication into the inhaler body of the '406 Publication, not moving the dose counter of the '406 Publication into the inhaler body of the '514 Publication. Tr. 576:16-578:9 (Anderson). Furthermore, in the absence of clarifying testimony, it is not clear whether the POSA would have interpreted the commercially available inhaler bodies mentioned in paragraph 105 of the '406 Publication to include ribs (since the '406

Publication does not), or whether, if so, the POSA would have understood paragraph 105 to imply, contrary to its express text, that the *internal* features (like ribs) of commercially available inhaler bodies could also remain unchanged. DTX-161 at [00105] ('406 Publication).

b. Dr. Lewis Explained Why the POSA Would Not Have Expected Cipla's Combination to Be Successful

120. Cipla's failure to adduce clear-and-convincing evidence regarding expectation of success is exacerbated by Dr. Lewis's consistent testimony that the POSA would not have expected the addition of rails to the '406 Publication's inhaler and dose counter to result in a functional inhaler.

121. Dr. Lewis explained that MDIs are designed to look simple, but are in reality "very complex." Tr. 145:5-14 (Lewis). They are difficult to design, because they must accommodate use by tens of millions of patients all with varying characteristics and unpredictable behaviors. Tr. 149:6-22 (Lewis). "10 to 20 million people" of varying ages and strengths will all do, as Dr. Lewis put it, "everything I can think of and . . . things I can't think of and wish I knew." Tr. 149:6-22. Inventor testimony confirmed this difficulty, noting that it was "very hard to develop a counter that would work with the users variable engagement with the product." Tr. 626:7-12 (Karg).

122. The POSA would have appreciated that mixing and matching different parts from different devices would not ordinarily work. Tr. 145:5-14 ("Most of the

time this is not going to work."), 703:6-13 ("[I]n the first instance, you can't take one device to another and combine it."), 706:15-21 ("[Y]ou can't mix and match things."). As the POSA would have understood, components of a system are designed to work together, making it "difficult to move to different components." Tr. 751:18-22 (Lewis); *see also* Tr. 659:1-4 (Karg) ("It was an entire system. The hardest part was understanding the interplay of all of the different components and then building a solution set that would work . . . for everything we had to modify.").

123. The POSA would have viewed adjusting a device with an internal dose counter as especially challenging, given the potential to affect drug delivery. Tr. 685:20-24 (Lewis). As Dr. Lewis explained:

> You start putting anything inside, you are going to change the flow path. Once you put a patient's mouth in front of this, there is going to be backflow. Anything you put upstream, it is going to have a big change in how, essentially, the medicine reaches the lungs.

Id. Drug delivery is the single most important feature of an MDI, and the POSA would have viewed changes that interfered with drug delivery as a "deal breaker." Tr. 684:21-685:6 (Lewis). In light of this concern, the POSA would have appreciated that the room for adjustment and error was very small-- "[a]ny changes," even "small changes" to product performance can prove "extremely important" or "potentially fatal"—and could entail 10 to 20 years of development work. Tr. 746:9-23 (Lewis).

124. Dr. Lewis thus testified that in his opinion, not only would the POSA have understood that the rails of the '514 Publication would not have fit into the

device of the '406 Publication, Tr. 703:6-709:8 (Lewis) ("it's not going to fit"), but also the POSA would have expected the combination of the '406 and '514 Publication would have "obstruct[ed] the movement of th[e] canister" in the '406 publication, and "add[ed] to the downsides of [the '406 Publication's] design poor airflow, restriction of drug delivery." Tr. 704:8-11, 794:21-23 (Lewis). In short, "none of this is going to work." Tr. 796:1 (Lewis). Against the backdrop of this testimony, Mr. Anderson failed to explain how the '406 Publication's device and the '514 Publication would or could have been altered to produce a functional product. Tr. 564:9-19, 576:4-6, 576:8-12, 577:13-578:9 (Anderson).

C. The Dependent Claims Would Not Have Been Obvious

125. Each of dependent claims 2, 4, 6, and 7 of the '289 Patent depend from claim 1, and therefore would not have been obvious over the combination of the '406 and '514 Publications for all the reasons described above. *Supra* § VII.B. In addition, the dependent claims are not obvious in view of the combination of the '406 and '514 Publications for the additional reasons described below.

1. Claim 2 Would Not Have Been Obvious

126. Claim 2 of the '289 Patent recites:

> 2. The inhaler as claimed in claim 1 wherein the medicament canister is movable relative to the dose counter.

JTX-003 ('289 Patent).

127. Cipla failed to prove by clear-and-convincing evidence that the POSA would have been motivated to combine the '406 and '514 Publications in a manner that would have led to a medicament canister that is moveable relative to the dose counter, as claim 2 of the '289 Patent requires.

128. If the POSA in 2010 decided to make an internal dose counter, the POSA would have chosen to affix the counter to the canister. *Supra* § VII.B.1.a.3).

129. Affixing the dose counter to the canister comes with substantial advantages—namely, it eliminates the potential for inaccuracy-inducing rocking between the canister and the dose counter, is particularly robust, and assists in handling and assembly of a complete dispenser, including by facilitating the insertion of the canister/counter assembly into the inhaler body. Tr. 259:1-260:6 (Lewis); DTX-165 at 7:20-27 ('514 Publication) ("The provision of a dispensing canister/indicator assembly as a self-contained or single unit in which the indicator is located substantially about the dispensing canister (e.g. the container of the canister and/or the canister closure means and above the outlet means of the canister is particularly advantageous because such an assembly is desirably robust. Furthermore such an assembly allows for desirable ease in handling and assembly of a complete dispenser. In particular the insertion of the outlet means into the support block of an adaptor is desirably facilitated for large scale assembly and more importantly if desired by a patient because the outlet means of the dispensing canister is unobstructed by components of a dose counter.").

130. As of the date of Teva's invention, there was one MDI with a dose counter on the market, called Seretide. Tr. 689:6-13 (Lewis). Seretide's dose counter was located inside the housing and was affixed to the canister. Tr. 689:14-690:9 (Lewis). If the POSA chose to make a counter and chose to locate it inside the inhaler housing, the POSA would have followed this approach. Tr. 690:10-691:4 (Lewis).

131. In addition, Cipla's sole theory of obviousness requires that the POSA would have added the rails of the '514 Publication to the inhaler body and dose counter of the '406 Publication. Tr. 563:21-564:4 (Anderson). If the POSA had chosen to rely on the '514 Publication, as Cipla's theory requires, the POSA would not have chosen to violate the core principle of operation of this reference by making a dose counter that was moveable relative to the medication canister. *Supra* § VII.B.1.c.2).

132. Cipla's design choice to utilize a dose counter that is moveable relative to the canister does not inform the decisions the POSA would have made as of 2010, nor suggest that in 2010, the POSA would have been motivated to combine the '514 Publication with the '406 Publication to create a dose counter that is moveable relative to the medication canister. *Supra* § II (explaining 2010 priority date). The POSA would not have done so, for the reasons explained *infra* in this Section.

2. Claims 4, 6, and 7 Would Not Have Been Obvious

133. Claims 4, 6, and 7 of the '289 Patent recite:

> 2. The inhaler as claimed in claim 1 wherein the medicament canister is movable relative to the dose counter.
>
> 4. The inhaler as claimed in claim 1, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body.
>
> 6. The inhaler as claimed in claim 4 further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body.
>
> 7. The inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other.

JTX-003 ('289 Patent).

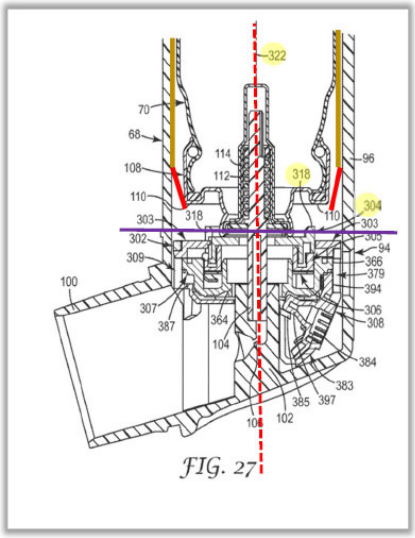
134. Each of claims 4, 6 and 7 requires one or more wall canister support formations that extend longitudinally along the inside wall of the inhaler body. JTX-003 ('289 Patent). Cipla failed to prove that the POSA would have arrived at an inhaler that meets this requirement by combining the '406 and '514 Publications, as Cipla's theory requires. Tr. 563:21-564:4 (Anderson).

135. The fact that the '514 Publication depicts rails that extend longitudinally along the inside of the inhaler body does not suggest that such rails would be similarly shaped if imported into the '406 Publication, because the record reflects that the support rails of the '514 Publication would not have fit into the inhaler body of the '406 Publication, Tr. 703:12-704:21, 706:9-21 (Lewis), and would have obstruct[ed] the movement of th[e] canister" in the '406 publication, and "add[ed] to the

downsides of [the '406 Publication's] design poor airflow, restriction of drug delivery," Tr. 704:8-11, 794:21-23 (Lewis).

136. Mr. Anderson failed to explain how the '406 Publication's device and the '514 Publication would or could have been altered to produce a functional product. Tr. 564:9-19, 576:4-6, 576:8-12, 577:13-578:9 (Anderson).

137. Mr. Anderson's only testimony relevant to this point was his suggestion that the image below (DDX3.32) reflects the manner in which the POSA would have combined the '406 and '514 Publications. And as we have been discussing, the '514 discloses the inner wall canister support formation. Tr. 569:11-24 (explaining that gold lines reflect inner wall of '406 Publication), 577:13-578:9 (describing the red ribs that come from the '514 Publication). This image does not depict rails extending longitudinally along the inside body of the inhaler.



DTX-161 ('406 Publication), Fig. 27 (annotated).

138. There is thus no evidence that if the POSA had chosen to add the ribs of the '514 Publication to the inhaler and dose counter of the '406 Publication, the resulting ribs would have extended longitudinally along the inside surface of the inhaler body after being modified to fit in the '406 Publication's inhaler. Cipla has therefore failed to prove that claims 4, 6, and 7 are obvious in view of the combination of the '406 and '514 Publications.

VIII. The Asserted Claims of the '587 Would Not Have Been Obvious

139. Claim 1 of the '587 Patent recites:

> 1. An inhaler for metered dose inhalation, the inhaler comprising:
>
> a main body having a canister housing,
>
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
>
> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
>
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
>
> wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and
>
> wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with

the longitudinal axis X such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.

JTX-004 ('587 Patent).

140. Claim 12 of the '587 Patent recites:

12. An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,

a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and

a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,

wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and

wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member.

JTX-004 ('587 Patent).

A. The Claims of the '587 Patent Contain Meaningful Limitations that the Claims of the '289 Patent Do Not

141. Claim 1 of the '587 Patent contains every limitation of claim 1 of the '289 Patent. Cipla therefore failed to prove claim 1 of the '587 Patent is obvious for all the reasons explained in Sections VII.A and VII.B. In addition, claim 1 of the '587 Patent contains a limitation that claim 1 of the '289 Patent does not: "such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler." *Compare* JTX-003 ('289 Patent, Claim 1) *with* JTX-004 ('587 Patent, Claim 1). Cipla failed to prove claim 1 of the '587 patent is invalid for the additional reason that it failed to address this additional "Rocking Limitation," as explained below.

142. Claim 12 of the '587 Patent contains every limitation of claim 1 of the '289 Patent. Cipla therefore failed to prove claim 1 of the '587 Patent is obvious for all the reasons explained in Sections VII.A and VII.B. In addition, claim 12 of the '587 Patent contains a limitation that claim 1 of the '289 Patent does not: "such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member." *Compare* JTX-003 ('289 Patent, Claim 1) *with* JTX-004 ('587 Patent, Claim 12). Cipla failed to prove claim 12 of the '587 patent is invalid for the additional

reason that it failed to address this additional "Rocking Limitation," as explained below.

143. The limitations of Claim 1 and Claim 12 of the '587 Patent have different scope—claim 1's reference to unwanted actuation of the dose counter refers only to overcounting errors, and it requires reducing rocking of the canister "relative to the main body of the inhaler." Tr. 272:1-276:15, 277:13-279:11 (Lewis); JTX-004 ('587 Patent, Claim 1). In contrast, claim 12's reference to "dose count errors" includes both under- and overcounting errors, but requires reducing rocking of the canister "towards or away from the actuation member." Tr. 272:1-276:15, 277:13-279:11 (Lewis); JTX-004 ('587 Patent, Claim 12).

144. However, Cipla makes the same argument with respect to both these limitations (that they are meaningless) and adduced no evidence of obviousness with respect to either of them. Tr. 583:3-21 (claim 1), 584:9-22 (claim 12) (Anderson). Thus, there is no need to distinguish between the scope of claim 1 of the '587 Patent and claim 12 of the '587 Patent for purposes of resolving the disputed issue of obviousness.

145. Dr. Lewis testified without contradiction that the Rocking Limitations impose meaningful structural limits on the MDIs that satisfy claims 1 and 12 of the '587 Patent. In other words, the fact that an MDI meets every limitation of claim 1 of the '289 Patent (including the Common Plane Limitation) does *not* mean it will also meet the rocking limitations. Tr. 181:3-182:4. That depends on the configuration of

the inner wall canister support formation and the MDI as a whole. *Id.* As Dr. Lewis explained:

> Q. And the mere fact, the fact that you have an inner wall canister support formation in a common plane, does that mean that that inner wall canister support formation necessarily protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the dose counter?
>
> A. It doesn't necessarily protect.
>
> Q. Does it depend on the configuration?
>
> A. Yes. Absolutely, yes.
>
> * * *
>
> Q. . . . [D]oes the extra language, the [Rocking Limitation] in Claim 1 of the '587 patent, does that impose an additional limitation on the structure of the inhaler that's not in the '289 patent?
>
> A. Yes, it does.

Id. Mr. Anderson did not contradict Dr. Lewis on this point. He stated that the Rocking Limitations "giv[e] a little bit more purpose, yet" to the Common Plane Limitation, but did not disagree with Dr. Lewis that there are inhalers that could infringe claim 1 of the '587 Patent without infringing claim 12 of the '587 Patent. Tr. 583:3-14. To the contrary, Mr. Anderson appeared to agree with this analysis, because he testified as follows when offering his noninfringement opinion.

> Q. Are there any additional limitations in '587 patent, Claim 1 that, in your opinion, aren't met by Cipla's ANDA device?

> A. The rocking.
>
> Q. Mr. Anderson, can you be a little more specific in terms of what limitation -- in the '587 patent, Claim 1, what additional limitations ae missing in Cipla's ANDA product?
>
> A. Yeah, such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.

Tr. 488:18-489:3. Thus, Mr. Anderson gave meaning to the Rocking Limitations on his infringement analysis that is in conflict with Cipla's position on invalidity that the Rocking Limitations are meaningless.

146. During claim construction, Cipla agreed to a construction for the Rocking Limitation of claim 1 as follows: "guards against unwanted actuation by reducing rocking of the medicament canister relative to the main body of the inhaler that would otherwise be of a magnitude sufficient to move the dose counter's actuator enough to cause unwanted incrementing (or decrementing) of the dose counter." D.E. 102, at 5. Cipla's agreement to that construction is inconsistent with Cipla's position that the Rocking Limitation is meaningless.

147. This evidence outweighs Cipla's reliance on the statement by the patent examiner that the Rocking Limitations recite only a purpose for the Common Plane Limitation. JTX-008, TEVAQVAR-00028882-2884 ('587 Patent File History). The examiner made that statement without the benefit of Dr. Lewis's testimony regarding the structural limits imposed by the Rocking Limitations and without the context of

Cipla's conduct during this litigation, which is plainly inconsistent with the examiner's interpretation. Furthermore, the examiner's rejection was preliminary and designed to ensure that the standard term of the '587 Patent did not extend beyond the term of the '289 Patent—Teva mooted that objection by filing a "terminal disclaimer" that ensured the two patents would have coordinated expiry dates. Filing a terminal disclaimer meant that Teva did not have a need to address the examiner's rejection on the merits, so the propriety of the examiner's statement was never fully vetted.

148. Accordingly, the Rocking Limitations impose meaningful limitations on the scope of claims 1 and 12 of the '587 Patent.

B. Cipla Offered No Evidence of Obviousness for the '587 Patent

149. Cipla failed to offer any evidence at trial regarding whether the combination of the rails of the '514 Publication with the inhaler body and dose counter of the '406 Publication would have satisfied these limitations. Tr. 583:3-21 (claim 1), 584:9-22 (claim 12) (Anderson). Cipla thus failed to prove by clear-and-convincing evidence that any asserted claim of the '587 Patent is invalid.

150. Claims 2, 4, 6, and 7 of the '587 Patent recite:

> 2. The inhaler as claimed in claim 1 wherein the medicament canister is movable relative to the dose counter.
>
> 4. The inhaler as claimed in claim 1, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body.

> 6. The inhaler as claimed in claim 4 further comprising a plurality of support rails each of which extends longitudinally along the inside surface of the main body.
>
> 7. The inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other.

JTX-004.

151. Each of claims 2, 4, 6, and 7 depends from claim 1 of the '289 Patent and therefore incorporates every limitation of claim 1. JTX-004. Thus, Cipla failed to prove that claims 2, 4, 6, and 7 are obvious for all the same reasons it failed to prove that claim 1 of the '587 Patent is obvious. *Supra* § VIII.A. In addition, each of claims 2, 4, 6, and 7 contains a dependent limitation that is substantially identical to the dependent limitation of the corresponding claim in the '289 Patent. *Compare* JTX-003 ('289 Patent) *with* JTX-004 ('587 Patent). Accordingly, each of claims 2, 4, 6, and 7 are not obvious for the additional bases explained in Section VII.C.

IX. Claim 28 of the '808 Patent Would Not Have Been Obvious

152. Asserted Claim 28 of the '808 Patent depends from claims 1 and 27 and further requires the "regulator" to provide a "resistance force" of "greater than 0.3 N." JTX-002, claims 1, 27, 28. Cipla failed to prove by clear-and-convincing evidence that claim 28 would have been obvious. *See infra* §§ IX.B.1-IX.B.5.

A. The POSA Would Not Have Been Motivated to Select the '406 and '552 Publications from the Sea of Prior Art

153. Dr. Lewis testified that a POSA would not have had a reason to select the '406 Publication in practicing the inventions recited in claim 28 of the '808 Patent. *See* Tr. 692:4-15 (Lewis).

154. Cipla did not adduce any evidence that a POSA would have had a reason to select the '406 Publication in practicing the inventions recited in claim 28 of the '808 Patent. *See, e.g.*, Tr. 544:13-605:12 (Anderson);

155. Cipla did not adduce any evidence that a POSA would have had a reason to select the '552 Publication in practicing the inventions recited in claim 28 of the '808 Patent. *See, e.g.*, Tr. 544:13-605:12 (Anderson);

B. Claim 28 of the '808 Patent Would Not Have Been Obvious Over the '406 Publication

1. Cipla Cannot Overcome a Failure of Proof

156. Mr. Anderson asserted in conclusory fashion that if Cipla's ANDA Products infringe claim 28 of the '808 Patent, then claim 28 would have been obvious over the '406 Publication. Tr. 563:9-15 (Anderson). Mr. Anderson's testimony lacks support and fails to rise to the level of clear-and-convincing evidence.

157. Cipla failed to prove by clear-and-convincing evidence that the '406 Publication renders obvious a "regulator" that provides a "resistance force" of "greater than 0.3 N." *See, e.g.*, Tr. 713:25-728:15 (Lewis); 71:6-72:10, 84:22-90:5 (Walsh); 636:2-637:13 (Karg); *infra* ¶¶ 158-180.

158. Cipla did not adduce any evidence that a POSA would have had a reason to select a resistance force of "greater than 0.3 N" as opposed to any other value. *See* Tr. 544:13-563:20 (Anderson); Tr. 714:19-715:14 (Lewis).

159. Mr. Anderson did not testify that a POSA would have had a reason to select a "resistance force" of "greater than 0.3 N." *See* Tr. 544:13-563:20 (Anderson); Tr. 714:19-715:14 (Lewis).

160. Mr. Anderson never testified that a POSA would have arrived at a resistance force of "greater than 0.3 N." *See* Tr. 544:13-563:20 (Anderson); Tr. 714:19-715:14 (Lewis).

161. Unrebutted evidence establishes that the '406 Publication does not render obvious a "regulator" that provides a "resistance force" of "greater than 0.3 N." *See, e.g.*, Tr. 713:25-728:15 (Lewis); 71:6-72:10, 84:22-90:5 (Walsh); 636:2-637:13 (Karg); *infra* ¶¶ 162-180.

162. To determine whether a spring or other purported "regulator" "provides" a "resistance force" of "greater than 0.3 N," a POSA would need to know the "material the spring is made out of," "the size of the spring" and the "scale of the relative components." Tr. 713:25-715:24 (Lewis).

163. The "optimal force for a regulator" depends on the "material the spring is made out of," "the size of the spring" and the "scale of the relative components." Tr. 713:25-715:24 (Lewis).

164. Whether or not 0.3 N is a very small number is irrelevant to whether the claimed inventions would have been obvious. A POSA would not select a resistance force of greater than 0.3 N" because increasing the resistance force would add to the "compression to the energy that the patient is going to need to push." Tr. 728:5-13 (Lewis).

165. Teva's research and development of the claimed inventions supports the nonobviousness of claim 28 of the '808 Patent. Teva's inventors discovered during "very late stage testing" in the research and development of the claimed inventions that "the counter display wasn't maintaining accuracy" "because it had the ability to move back and forth of its own accord." Tr. 85:22-90:5, 71:6-72:10 (Walsh), 635:12-637:13 (Karg).

166. Before implementing the claimed "regulator" with its specific resistance force, the inventors considered multiple design alternatives; in a parallel project, the inventors considered at least "six" such alternatives. *See* Tr. 86:23-90:6 (Walsh); PTX-247 (Brainstorm).

167. Teva hired Radius Innovation, including inventors Mr. Karg and Mr. Uschold, because its own engineers could not solve the problems presented in researching and developing the claimed inventions. *See* Tr. 64:22-66:10 (Walsh).

168. Teva's inventors had concerns that increasing the resistance force" would prevent the device from functioning correctly; because of how the "regulator" interacted with other small, "fragile" components, the inventors "had to find a very

fine balance between protecting all the small parts so that they wouldn't break, yet still constrain the rotation enough so that the counter display could not freely rotate." Tr. 636:2-637:13 (Karg); *see also* Tr. 728:5-13 (Lewis).

169. The size and scale of MDIs and dose counters confirms that whether or not 0.3 N is a small value does not mean that it would have been obvious. The part of the dose counter that contains the regulator is "a quarter of a size of a matchbox" and has "over 100 dimensions." Tr. 84:11-85:21 (Walsh); PTX-231, at TEVAQVAR-00462027 (Engineering Drawing).

170. Even developing a preliminary understanding of the relevant part interactions and "knock on effects" required running "thousands and thousands" of mathematical models using cutting-edge software. *See* Tr. 632:9-25 (Karg); PTX-223 (CETOL Model).

171. Teva's inventors testified that the research and development project that led to the claimed inventions was one of the most "complex" projects of their careers. Tr. 96:14-97:17 (Walsh); 637:17-638:9 (Karg).

172. Cipla did not adduce any contrary evidence. *See, e.g.*, Tr. 544:13-563:20 (Anderson).

2. Cipla Failed to Prove that the '406 Publication's Disclosed Embodiments Are the "Same As" Cipla's Product

173. Mr. Anderson failed to offer any adequate explanation for his assertions that Cipla's product has "every single component" that the '406 Publication discloses

and that those components are the "same." Tr. 560:1-4, 560:20-25, 563:12-15 (Anderson).

174. Dr. Lewis's testing of Cipla's product (*see* D.E. 262, at 39-42) does not establish that the '406 Publication's disclosed embodiments and Cipla's product are the same; the amount of force that Cipla's leaf spring exerts does not establish that the '406 Publication's disclosed embodiments exert the same amount. Rather, to know that, the '406 would have needed to disclose information that it does not. *See* Tr. 713:25-715:24 (Lewis); supra ¶ 162.

175. Mr. Anderson did not testify at trial as to any experiments he conducted regarding the amount of "resistance force" that the '406 Publication's disclosed embodiments or Cipla's product exert. *See* Tr. 544:13-563:20 (Anderson).

176. Dr. Lewis's testimony acknowledging that the '406 Publication's disclosed embodiments and Cipla's device had "similarities" does not preclude differences, nor does it establish that the '406 Publication renders obvious a "regulator" that "provides" a "resistance force" of "greater than 0.3 N." Tr. 745:20-746:1, 753:1-8, 758:1, 762:16-23 (Lewis) ("[T]he five embodiments in the '406 [Publication] are very, very different . . . .").

3. Cipla's Routine Optimization Theory Is Based on Hindsight

177. Mr. Anderson's testimony regarding routine experimentation was based on hindsight.

a. Mr. Anderson's only testimony regarding routine experimentation addressed whether claim 28 would have been obvious based on the '552 Publication. Mr. Anderson did not address whether a POSA would have arrived at the claimed "resistance force" based on the '406 Publication. Tr. 555:21-558:3 (Anderson); DDX3.16.

b. Mr. Anderson also relied entirely on the '808 Patent's own explanation of how the inventors arrived at the claimed "resistance force." *See* Tr. 555:21-558:3 (Anderson); DDX3.16 (citing JTX-002, at 19:28-37 ['808 Patent]).

'808 Patent

transit or if the inhaler **12** is dropped. It has been found during testing that a force of 0.3 to 0.4 N needs to be applied to the tape **112** to overcome the regulator at the stock bobbin **110**. 0.32 N is achieved with the control elements **128** having the profile shown in FIG. **19**C and 0.38 N is achieved with the profile of the control elements **128** altered to be as shown as described with reference to FIG. **6**F. These forces are substantially higher than the 0.1 N force mentioned above and undesirable movement of the tape is substantially avoided even if the inhaler is dropped onto a hard surface.

JTX-002 ('808 Patent), 19:28-37 (highlighted).

c. Mr. Anderson admitted that he relied on the '808 Patent's own explanation during cross-examination:

Q. Why did you decide to rely on the specification of the patent?

A. Because it guides you. It informs you, and some of it is experimental, but some of it is very, very well defined. And they actually provide you charts showing the tolerances that they then worked to, and they give you nominals as well to work from.

Tr. 555:21-558:3 (Anderson); DDX3.16

178. Cipla did not adduce any evidence that a POSA would have arrived at a "regulator" that "provides" a "resistance force" of "greater than 0.3 N" through routine experimentation. *See* Tr. 544:13-563:20 (Anderson); Tr. 715:12-17 (Lewis).

179. The '808 Patent states that the inventors "found during testing that a force of 0.3 to 0.4 N" needed to be applied in the case of the particular embodiment described in Figures 18C and 19C. JTX-002, at 19:28-37 ('808 Patent).

180. Dr. Lewis's testimony that a POSA would have been able to "calculate" the "resistance force" imparted by a given spring as of the priority date, Tr. 757:10-13 (Lewis), does not establish that a POSA would have arrived at a resistance force of "greater than 0.3 N."

4. Claim 28 of the '808 Patent Would Not Have Been Obvious Over the '552 Publication

181. Cipla failed to prove by clear-and-convincing evidence that the '552 Publication renders obvious a "regulator" that provides a "resistance force" of "greater than 0.3 N." *See, e.g.*, Tr. 713:25-728:15 (Lewis); 71:6-72:10, 84:22-90:5 (Walsh); 636:2-637:13 (Karg); *infra* ¶¶ 182-185.

a. Unrebutted Evidence Establishes that Claim 28 of the '808 Patent Would Not Have Been Obvious Over the '552 Publication

182. Unrebutted evidence establishes that the '552 Publication does not render obvious a "regulator" that provides a "resistance force" of "greater than 0.3

N." *See, e.g.*, Tr. 713:25-728:15 (Lewis); 71:6-72:10, 84:22-90:5 (Walsh); 636:2-637:13 (Karg).

a. The '552 Publication does not disclose any "numerical resistance force" or even "what forces would be required." Tr. 727:10-728:15 (Lewis).

b. As with the '406 Publication, a POSA would understand that increasing the resistance force would have been undesirable because it would increase the "energy that the patient is going to need to push." Tr. 728:5-13 (Lewis).

c. The inventors testified that not even they were aware of the problem the "regulator" solved until late in development—much less, the specific "resistance force" needed to solve it. *See* Tr. 85:22-90:5, 71:6-72:10 (Walsh), 635:12-637:13 (Karg).

b. Cipla Failed to Prove that a POSA Would Have Arrived at the Claimed Invention Through Routine Experimentation

183. Cipla failed to prove that a POSA would have arrived at a "regulator" that "provides" a "resistance force" of "greater than 0.3 N" through routine experimentation. See *supra* § IX.B.3. Mr. Anderson's testimony regarding routine experimentation relied impermissibly on the '808 Patent's own explanation of how the inventors arrived at the claimed resistance force. See id.

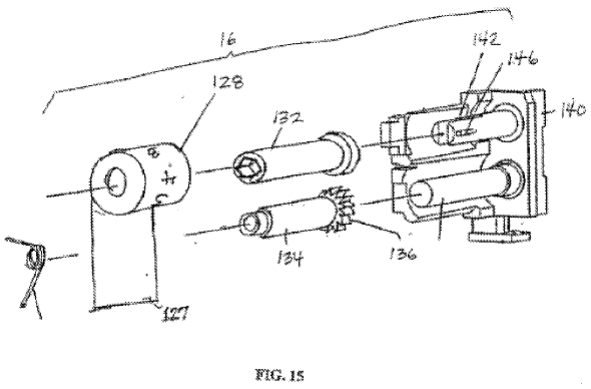
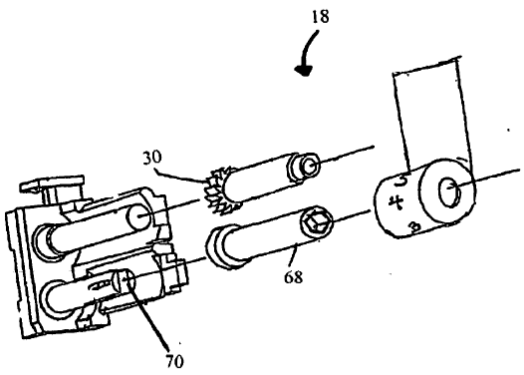
184. Whether or not inhalers or dose counters are commonly subjected to forces of greater than 0.3 N does not establish that a POSA would have had a reason to increase the "resistance force" of "greater than 0.3 N." Tr. 728:5-15 (Lewis); Tr. 636:25-637:13 (Karg).

185. Dr. Lewis's testimony that ProAir® and Qvar®'s devices embody the Asserted Claims does not establish that the '552 Publication renders obvious a "regulator" that provides a "resistance force" of "greater than 0.3 N." Mr. Walsh was the lead inventor of the '808 Patent and was personally involved in the development of Teva's devices. JTX-002 ('808 Patent); Tr. 63:2-14, 84:11-87:6 (Walsh). He testified that Teva's engineering drawings (PTX-231) described the actuator body and dose counter that he and his team invented, including the claimed "regulator." Tr. 84:11-87:6 (Walsh); PTX-231, TEVAQVAR-00462027 (Engineering Drawing). Thus, Dr. Lewis had no reason to conduct testing in the case of Teva's devices.

5. The Patent Trial and Appeal Board's Decision Supports the Nonobviousness of Claim 28 of the '808 Patent

186. During prosecution, the examiner rejected the pending claims of the '808 Patent (including Asserted Claim 28) over U.S. Patent Application Publication No. 2002/0078950 (the "'950 Publication") (which the examiner referred to as "O'Leary"). *See* JTX-006, at TEVAQVAR-00027224-26 (Board Op.).

187. Figure 15 of the '950 Publication, which the examiner cited, is materially the same as Figure 6 of the '552 Publication, which Mr. Anderson relied upon at trial:

’950 Publication, Fig. 15	’552 Publication, Fig. 6
 FIG. 15	6/8  Fig. 6

JTX-006, TEVAQVAR-00027225 (Board Op.); DTX-162, at 24 (’552 Publication); Tr. 555:21-558:3 (Anderson); D.E. 157, ¶ 151 (Anderson Reply Rep.) (Ex. A).

188. In his expert reports, Mr. Anderson advanced obviousness theories based on both the ’950 and ’552 Publications; both in his expert reports and at trial, he admitted that the ’950 and ’552 Publications “disclose the same configuration.” *See* JTX-006, TEVAQVAR-00027226 (PTAB Op.); DTX-162, at 24 (’552 Publication); Tr. 586:11-587:15 (Anderson); D.E. 157, Table of Contents, ¶¶ 151 (Anderson Reply Rep.) (Ex. A). Dr. Lewis testified that the ’950 and ’552 Publications contained materially the same disclosure. *See* Tr. 724:24-728:15 (Lewis).

189. The Patent Trial & Appeal Board (“PTAB”) reversed the examiner’s rejection, holding that O’Leary did not provide enough information to determine that its bobbin 132 (which is analogous to the ’552 Publication’s stock bobbin 68) whether

O'Leary's device would "necessarily result in incremental movement." JTX-006, TEVAQVAR-00027226 (Board Op.).

190. The PTAB's decision, JTX-006, TEVAQVAR-00027226 (Board Op.), contradicts Mr. Anderson's assertion that the '552 Publication discloses a "regulator" because it depicts "projections [on 70] and a surface for the projections [inside 68] to actually physically engage with." Tr. 555:10-18 (Anderson).

191. Dr. Lewis's testimony regarding "roundabouts" does not contradict the PTAB's decision. Dr. Lewis referred to "roundabouts" in order to explain that forces could operate "against movement of the counter display" (as claim 28 requires) without being applied in a direction opposite the counter display's movement. *See* Tr. 315:2-24 (Lewis). Dr. Lewis's analogy about the direction of force does not relate to claim 28's requirement that the "regulator" regulate or modulate the movement of the "counter display" to "incremental movements."

192. The '552 Publication's statements that in certain embodiments, (1) the "dose counter further comprises a stock bobbin to receive the counter tape as the indexing spool is advanced in a step-wise fashion," DTX-162, at 9:9-17; and (2) the "spindle of the rotary gear moves the counter tape 44 revealing the next integer," DTX-162, at 10:6-8, does not establish that the '552 Publication discloses the claimed "regulator."

193. Mr. Walsh and Mr. Karg did not admit that the '552 Publication discloses a regulator. In fact, they testified that the inventors discovered the regulator

during "very late stage testing" after the '552 Publication published. *See* Tr. 635:14-637:13 (Karg); Tr. 84:11-87:6 (Walsh); DTX-162 ('552 Publication); PTX-231, TEVAQVAR-00462027 (Engineering Drawing); *supra* § IX.B.4.

194. Teva's engineering drawing (PTX-231) depicting the claimed "regulator" was created in November 2009, after the '552 Publication, assigned to Ivax, a Teva company, was filed on April 1, 2008. *See* DTX-162 ('552 Publication); PTX-231, TEVAQVAR-00462027 (Engineering Drawing). Teva could not have disclosed a regulator in April 2008 because it had not yet invented one.

X. Witness Credibility

195. Cipla's Proposed Findings of Fact contain a series of erroneous attacks on Dr. Lewis's and Mr. Karg's credibility. *See* D.E. 257, § IX. The Court does not need to address Cipla's criticisms because Cipla adduced no contrary evidence on the relevant issues. *See supra* §§ IV-IX; D.E. 263. Indeed, Cipla's own expert, Mr. Anderson, offered only conclusory testimony in response (including on obviousness, an issue on which Cipla bears the burden of proof by clear-and-convincing evidence, *see, e.g.*, *supra* §§ VII.B, IX.B, and repeatedly contradicted his own sworn testimony, *see* Tr. 602:9-604:9 (Anderson); D.E. 263, ¶¶ 79-83. Nevertheless, both Dr. Lewis and Mr. Karg testified credibly as to the infringement (in the case of Dr. Lewis) and nonobviousness (in the case of both) of the Asserted Claims.

A. Dr. Lewis Testified Credibly

196. Dr. Lewis has more than twenty-five years' experience developing metered dose inhalers and has led research and development of metered dose inhalers at multiple multi-national pharmaceutical companies. *See* Tr. 125:1-136:21 (Lewis); PTX-026 (Curriculum Vitae). Dr. Lewis testified credibly as to the differences between the '406 Publication and Cipla's product. As Dr. Lewis noted, there are visible differences between the '406 Publication's figures and Cipla's product, including with respect to the metering valve. *See, e.g.*, Tr. 746:24-748:10, 748:15-20 (Lewis); DTX-161, Figs. 21, 27 ('406 Publication); PTX-411 (Cipla ANDA Product Sample); PTX-372 (Cipla Design Drawing). As a result of these differences, *see supra* §§ VII.B, IX.B, a POSA would not have viewed the Asserted Claims as obvious even though Cipla's product infringes the asserted claims.

197. Dr. Lewis further testified credibly that the fact that the examiner did not cite the '406 Publication during prosecution of the Asserted Claims demonstrates that the Asserted Claims would not have been obvious. *See* Tr. 753:1-8. (Lewis). The '406 Publication's failure to disclose or suggest support rails or the information needed to determine the "resistance force" exerted by its spring; thus, there is no reason for the examiner to have cited it. That there are also similarities between the '406 Publication's figures and Cipla's device does not address those issues; and Cipla's assertion (D.E. 257, ¶ 207) that the '406 Publication and Cipla's device are the "same" lacks any basis in the evidence.

198. Dr. Lewis testimony was consistent with his prior publications. As Dr. Lewis testified, a POSA would not have had a reason to add support rails to the '406 Publication's disclosed embodiments, Tr. 746:24-748:10 (Lewis), because the '406 Publication's design "works without stabilization. It's stabilized because of the valve design," Tr. 748:15-20 (Lewis). Cipla asserts that Dr. Lewis's testimony is inconsistent with his other patents and publications, which describe or depict ribs in other devices, D.E. 257, ¶ 209 (citing PTX-099, CIPLA-BDI_0184749; DTX-223 at [0026]). No inconsistency exists. Dr. Lewis explained why, in the '406 Publication's disclosed embodiments, a POSA would not have had a reason or motivation to make that particular modification because it would not have made sense.

199. Cipla also misconstrues Dr. Lewis's testimony regarding whether the Common Plane Limitation would have been obvious based on combining the '406 and '514 Publications. *See* D. I. 257, ¶ 208. In his infringement analysis, Dr. Lewis testified that the Common Plane Limitation required drawing a line through an "inner wall canister support formation," "actuation member," and "center of the central outlet port." *See* Tr. 176:4-8, 209:3-210:1 (Lewis). Cipla takes issue with Dr. Lewis's refusal to agree with Cipla that combining the '406 and '514 Publications would result in the Common Plane Limitation. But as Dr. Lewis explained, a POSA not only *would not* have made that combination because the '406 Publication does not require stabilization and would have expected ribs to create additional problems, *supra* VII.B.1.b, but also *could not* have made that combination because the devices were

incompatible—"it wouldn't work" because you could not "get the can in." Tr. 796:6-21 (Lewis). Dr. Lewis's testimony was both responsive and supported by the evidence. Of the experts, only Dr. Lewis provided any analysis of whether a POSA would have had a reason to combine Cipla's asserted references with a reasonable expectation of success.

200. Dr. Lewis also testified credibly that Teva's ProAir® and Qvar® products satisfy the Asserted Claims. *See* Tr. 728:16-25 (Lewis). Cipla asserts that Dr. Lewis's testimony was not credible because he did not perform testing to determine whether they contained a "regulator." D.E. 257, ¶ 210. However, no testing was needed under the circumstances. Mr. Walsh, who was the lead inventor of the '808 Patent and was involved in the development of Teva's devices, testified that Teva's engineering drawings (PTX-231) described the actuator body and dose counter that he and his team invented, including the claimed "regulator." Tr. 84:11-87:6 (Walsh); PTX-231, TEVAQVAR-00462027 (Engineering Drawing). Whether such testing would have been difficult does not undermine Dr. Lewis's testimony or suggest that the Asserted Claims are invalid.

B. Mr. Karg Testified Credibly

201. Mr. Karg testified credibly regarding the discovery of the problem that led to the development of the support rails in the Common Plane Limitation.

202. Mr. Karg testified that the inventors discovered the problem with canister rocking during late stage development after performing a "sensitivity analysis"

and changed the configuration of the support rails as a result. *See, e.g.*, Tr. 633:1-635:8 (Karg). He further testified that, before that, the inventors were not aware of a problem that would require changing the configuration of the support rails. *See id.*

203. Cipla asserts that Mr. Karg's testimony was contradictory because he admitted that the software (CETOL and MathCAD) used to perform the sensitivity analysis did not account for canister tilt. *See, e.g.*, D.E. 257, ¶ 202. However, Mr. Karg actually testified that the inventors "used CETOL and other tolerance analysis sensitivity kind of analysis to point us in the right direction" and that the changes to the configuration of the support rails was based on their "directional interpretation of the CETOL model and the MathCAD model." Tr. 663:12-665:8 (Karg). That testimony is not contradictory.

204. Cipla also asserts that Mr. Karg's testimony was contradicted by Mr. Walsh who testified that the existing Teva devices contained support rails. D.E. 257, ¶ 203. Mr. Walsh did not contradict Mr. Karg. Mr. Walsh testified that, in addition to changing the positions of the existing rails, the inventors added "additional rails," *e.g.*, Tr. 77:17-78:18 (Walsh), which is consistent with Mr. Karg's testimony.

205. Mr. Karg also credibly testified as to the existence of prior art inhalers that did not contain support rails. After initially responding negatively to a question asking whether he was aware of inhalers that did not rely on support rails to prevent canister rocking, he identified a prior art inhaler (Flovent) that did not rely on support rails to prevent canister rocking because of its "unibody construction." Tr. 635:9-11,

638:13-639:7 (Karg). He further clarified that he "did not hear" the original question correctly. Tr. 639:10-14 (Karg).

206. Cipla's remaining criticisms (DI. 257, ¶¶ 204-206) attempt to cast down on Mr. Karg's recollection of specific dates that occurred more than a decade ago. Given the passage of time, those criticisms do not provide any reason to doubt Mr. Karg's testimony regarding the difficulty of the claimed inventions. Moreover, the fact that Teva had developed certain drawings by December 2009, does not undermine Dr. Karg's testimony that the development of Teva's devices was a process. *See* D.E. 257, ¶¶ 204-206.

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Respectfully submitted,

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